An Investigation into Footwear Materials Choices and Design for People Suffering with Diabetes

By

Jerry Irmiya Tagang

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Faculty of Art, Design and Humanities,

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Abstract

Use of appropriate footwear among diabetics and those with diabetic foot problems has been well documented to play a vital role in the prevention and treatment of established foot disease. The incidence and prevalence rates of diabetes in Africa are increasing and foot complications are rising parallel. Nigeria is Africa's most populous nation which also has the highest number of people (up to 3 million) suffering with diabetes in the continent. This is related to the lifestyle of the people which is changing including diet. Many urbanites are embracing Western way of living. There is however lack of adequate knowledge about the role of footwear in the management of foot related problems among diabetic patients in the country. This study is the first of its kind to be done in Nigeria with an aim to develop a framework that would help to identify appropriate footwear materials and designs for people suffering with diabetes. To achieve this, data were collected through questionnaire and interview surveys, shoe upper materials analysis and foot measurements. In addition, Product Design Specification (PDS) and design framework were formulated. And functional footwear prototypes were designed, constructed and assessed.

The data from the questionnaire survey indicate that up to 75% of the diabetic subjects have not received information about the type of footwear they should wear most often. The study revealed that the patients have very poor knowledge about diabetes and its complications, foot care, and the use of appropriate footwear. It was discovered that up to 53% female and 37% male of the patients were wearing slippers most often. Similarly, the findings from the medical doctors interviewed show that up to 66% of the patients were wearing slippers or slip-on (with no fastening mechanism) most often. The research revealed that financial constraint was a key factor to use of appropriate footwear by the patients. Many use cheap footwear regardless whether they provide the required protection and comfort to their feet or not. It was found out that specialist knowledge among medical doctors regarding foot care and provision of special footwear like orthopaedic and diabetic footwear to patients was very low.

The shoe upper materials analyses demonstrated that leather has good physical properties required for making diabetic footwear. Data from the measurement of feet indicated that no individual's feet are exactly the same even as people wearing the same shoe size might not have the same foot dimensions. It was concluded that these differences could have considerable effects on the shoe wearer. From the measured values, the tolerable allowance was found to be 3.4mm and 3.5mm for male and female subjects respectively. The fitting and comfort assessment of the prototypes have shown that some parts of the last used to make the prototypes would require amendments in order to accommodate minor foot deformities properly.

The findings from the research were used to develop PDS and a research framework which could be used as a guide for diabetic footwear design and construction. Finally, the contributions of this research to knowledge and critical areas that would require further investigations were outlined.

Key Words: Diabetes, Foot Problems, Footwear, Diabetic Footwear, Footwear Materials, Nigeria.

Examiners

External Examiner

Dr. Martin Evans

Lancaster University, UK.

Internal Examiner

Prof. Peter Ford

De Montfort University, Leicester.

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Used Acronyms and Abbreviations

ABUTH Ahmadu Bello University Teaching Hospital

CAD Computer Aided (or Assisted) Design

CAM Computer Aided Manufacture

DMU De Montfort University

DNM Do Not Want to Mention

IULTCS International Union of Leather Technologists and Chemists

NILEST Nigerian Institute of Leather and Science Technology

PDS Product Design Specification

SATRA Shoe and Allied Trade Research Association

SON Standards Organization of Nigeria

SOP Standard Operating Procedure

TA Tolerable Allowance

WVA Water Vapour Absorption

WVP Water Vapour Permeability

2D Two Dimensional

3D Three Dimensional

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Chapter 1: Introduction

1.1 Introduction/ Overview

There is still lack of adequate knowledge about the role of footwear for the management of diabetic related foot problems among patients and health care providers in Nigeria leading to further foot complications among patients in the region. But it has been discovered that proper footwear can have a significant influence on the well-being of diabetic patients (Pezza 2011). Therefore, this study focuses on footwear materials selection and design that could provide diabetic patients in Nigeria and probably other developing countries with appropriate footwear for maintenance or improvement of foot health.

All the research activities and outcome are put together in this thesis which consists of five major sections. The first section (chapter 1) would focus on general introduction, background, motivation, aim/ objectives, methodology, time management and the research structure. Following the introduction section is the literature review (chapter 2) of the subject matter. Another section dealing with the surveys and experimental analysis (chapter 3-6), development of the trial prototype and evaluation (chapter 7) would form a substantial part of this research thesis. The results obtained from the surveys and experimental analysis would be discussed in a separate section (chapter 8). And a final section on conclusion, and recommendations (chapter 9) for further research work would be outlined.

1.2.0 Background

1.2.1 Diabetes

Diabetes is described as a group of diseases marked by high levels of blood glucose resulting from defects in insulin production, insulin action, or both (Sharp 2011; Forth

2011). The disease is a global epidemic with devastating human, social and economic consequences (Bakker 2011). It can lead to serious complications and premature death, but people with diabetes, working together with their health care providers, can take definite steps to control or manage the disease and lower the risk of complications (National Diabetes Fact Sheets, 2011). Diabetes mellitus has been identified (Vernon 2007) as one of the commonly encountered diseases that may put the foot at risk. Findings from a study conducted by Mayfied and his colleagues (2000) suggest identification of a foot problem by clinicians should be followed by appropriate treatments including prescription of appropriate footwear in order to prevent serious complications.

1.2.2 Global prevalence of diabetes and diabetic foot problems.

The rising prevalence of diabetes worldwide will lead to an increasing prevalence of complications (Forlee 2010; Sheridan 2012) such as those of the lower extremities. According to Krentz and Bailey (2001), the prevalence of Type 2 diabetes increases with age; up to 20% of those over 80 years old develop diabetes. Therefore, the ageing populations of many societies have contributed substantially to the overall increase in the number of patients with diabetes. And in recent years the emergence of Type 2 diabetes in younger groups, including children, adolescents and young adults has been recorded (Krentz and Bailey 2001).

Diabetic patients have an approximately 15 fold increased risk of non-traumatic lower-limb amputation compared with the non-diabetic population. In elderly patients with Type 2 diabetes, there is a significant mortality rate associated with such major amputation. In the UK, foot complications remain the most common reason for the hospitalization of diabetic patients (Erasmus & Jorgensen 2008; Krentz & Bailey 2001; and Bodansky 1989). And in the developing countries, Aboderin and his colleagues (2002) reported that the number of people with diabetes will increase by more than 2.5 fold, from 84 million in 1995 to 228 million in 2025.

The most common consequences of diabetic neuropathy are amputation and foot ulceration. A recent research on diabetic foot complications by White (2010) has shown that the risk of ulcers or amputations increases the longer someone has diabetes and that early recognition and management of risk factors can prevent or delay adverse outcomes. Furthermore, it has been reported (Bakker 2011; White 2010) that 50% to 80% of all amputations are diabetes related and majority of these amputations are preceded by ulcers and that only two-thirds of ulcers will eventually heal. The outcome of ten years study (1996-2006) conducted by Witso et al. (2010) also show that diabetic lower-limb amputations accounted for one-third of all lower limb amputations.

According to Boulton and other researchers (2005), diabetic foot problems are common throughout the world, resulting in major economic consequences for the patients, their families, and society. About 25-90% of amputations in the world are associated with diabetes and it is believed that every 30 seconds a lower limb is lost somewhere in the world as a consequence of diabetes. Therefore, Wild and his co-researchers (2004) concluded that the world is facing an epidemic of Type 2 diabetes and increasing cases of Type 1 diabetes and that the lifetime risk of a person suffering with the disease developing a foot ulcer could be as high as 25%. The greatest rise in the prevalence of Type 2 diabetes is likely to be in developing countries in Africa, Asia, and South America, countries in which foot ulcers are more likely to be of neuropathic origin (Boulton, et al. 2005). In addition, Forlee (2010) noted that the rising epidemic of diabetes in the world, especially in the less developed world, will ensure that the incidence of foot complications will continue to increase in the diabetic population.

The spectrum of foot problems actually varies in different regions of the world due to differences in socio-economic conditions, standards of foot care and quality of footwear (Bakker, et al. n.d). A global view of diabetes and its complications according to different continent is presented thus:

Africa: Diabetes is one of the leading health problems in Africa which has reached epidemic proportion in the continent over a decade ago. The incidence and prevalence rates of the disease in the continent are increasing and foot complications are rising parallel (Abbas & Archibald 2007). It is predicted (Bahendeka 2010) that Sub-Sahara Africa which contains 33% of the poorest countries in the world, will experience the greatest rise in the prevalence of diabetes in the next 20 years. It was estimated that 14.7 million adults in Africa had diabetes in 2011 with a regional prevalence of 3.8% (fig. 1.1 gives a comparative prevalence of the disease in the continent). Some of Africa's most populous nations have the highest number of people with the disease (IDF 2013). The IDF report shows that Nigeria has the highest number (3 million), followed by South Africa (1.9 million), Ethiopia (1.4 million), and Kenya (769,000). The continent also has the highest proportion of undiagnosed diabetes, at least 78%. An estimated 344,000 deaths in the region can be attributed to diabetes. The report by IDF indicates that research, investment, and health systems are slow to respond to this challenge but remain focused primarily on infectious diseases. The Region accounts for less than 1% of world healthcare expenditures due to diabetes.

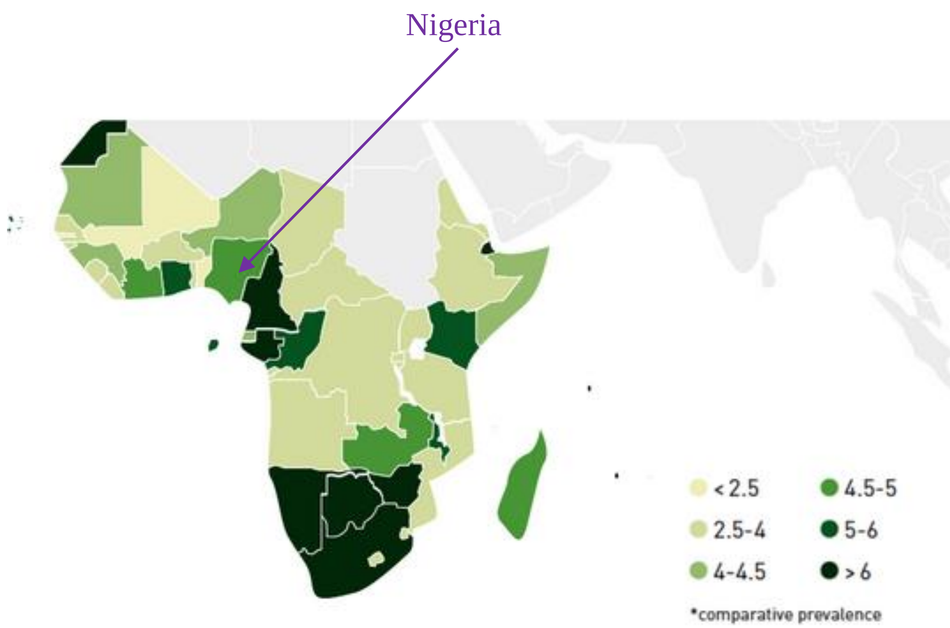


Fig. 1.1 Africa Region prevalence* (%) estimates of diabetes (20-79 years). IDF Diabetes Atlas (2013). http://www.idf.org/diabetesatlas/5e/africa.

And a cross-sectional hospital based study conducted by Unachukwu and his colleagues (2006) in Port Harcourt, Nigeria shows 38.1% prevalence of diabetic mellitus among medical in-patients, while foot ulcers was 19.1% among diabetic patients. However, despite some local data, the burden of diabetes in Africa is difficult to estimate (Mbanya et al. 2006)

According to Abbas and Archibald (2007), the reasons for poor outcomes of foot complications in Africa and in various less-developed countries include the following:

- Lack of awareness of foot care issues among patients and health care providers alike,
- Very few professionals with an interest in the diabetic foot or trained to provide specialist treatment,
- Non-existent podiatry services,
- Long distances for patients to travel to the clinic,
- Delays among patients in seeking timely medical care or among untrained health care providers in referring patients with serious complications for specialist opinion,
- Lack of the concept of multidisciplinary approach,
- Absence of training programs for health care professionals.

It is strongly believed that many governments in Africa currently are doing little or nothing to fight the problem of diabetes. There is little public health information about the disease and many people wait until it is too late to seek medical attention. In fact, for many people in the region, diabetes is not a major concern. Biriwasha (2009) points out that diabetes in Africa is a silent killer and that long-terms cost of non-action will be huge. He advocates that fight against the disease should be everyone’s business. In addition, it has been revealed (Morbach 2003) that problems associated with diabetic foot are worldwide, but that provision of professional diabetic foot care and wearing of protective diabetic footwear is completely uncommon in Africa.

Rest of the World: In view of the vast population of the Asian continent, data about diabetic foot problems are poor or sparse. It has been reported by Wild (2004) that India has more people with diabetes than any other country and foot problems and amputations remain very common. The work of some researchers (Boulton et al. 2005) indicates that interest in the diabetic foot is now growing in Asia and some centers have established multidisciplinary teams. Their research equally shows that barefoot gait is common and social and cultural beliefs can lead patients to seek help from traditional healers or village elders. According to Kari (2010) eighty percent of diabetic foots are neuropathic (which leads to loss of sensation in foot) in India.

Interest in diabetic foot problems is increasing in most parts of Europe with establishment of multidisciplinary foot-care teams which usually provide or advise patients of the type of footwear to use to avoid foot problems (Boulton et al. 2005). The European Union gives special attention to solving the problems of diabetic foot problems by sponsoring a research project (SSHOES Project) to design and develop new sustainable product concepts, such as footwear and insoles for diabetic feet (S-Shoes 2012).

In the U. S. A, diabetic foot complications are considered as the major cause of hospital admission. The statistic indicates that nearly 70% of all amputations were for people with diabetes. It has been found out that foot problems are more common in ethnic minority groups (like Hispanic and black people) who are less likely to have health insurance. In the Caribbean, diabetic foot problems and amputations are among the highest in the world. The prevalence of diabetes in this region is high, ranging from 5% to 20% but of recent, diabetic foot interest groups are being formed in different countries of the region (Boulton et al. 2005).

The International Diabetes Federation (2005) gives global guideline on foot care and classification of risk factors as follows;

No added risk: If no loss of sensation, no signs of peripheral arterial disease, and no other risk factor.

At risk: If neuropathy or other single risk factors are identified. Regular review should be arranged, approximately 6 months by foot-care team. At each review: both feet should be inspected, evaluate footwear and provide appropriate advice.

High risk: Diminished sensation plus foot deformities or evidence of peripheral arterial disease. Arrange frequent review every 3-6 months by foot-care team and at each review; both feet should be inspected and footwear evaluated.

Very high risk: Previous ulceration or amputation. The patient should be referred to a multidisciplinary foot-care team and specialist footwear and orthotic care provided.

1.2.3 Multidisciplinary approach to management of diabetes foot problems.

Teams providing foot care and footwear are becoming much more multidisciplinary in nature. The role perform by multidisciplinary teams in the treatment of diabetic foot problems has been shown (Tyrrell & Carter, 2009) to improve results and increase patient satisfaction with footwear. It is expected that each professional member of the team should bring his or her expertise for the overall well-being of the patient. To achieve this, all the professional members of the team should communicate well with one another in order to be able to develop an overall strategy. Nather and his colleagues (2010) pointed out that multidisciplinary diabetic foot team would typically comprise of an orthopaedic surgeon, a vascular surgeon, infectious diseases specialist, endocrinologist, podiatrist, and a nurse. And some multidisciplinary teams have included shoemakers and orthotists to make special footwear and orthoses for patients to prevent foot ulcers and injuries. In fact, the team approach is probably more beneficial to the successful treatment of the diabetic foot than almost any other problem the physician encounter (Janisse & Janisse 2006).

A previous study (Ellis et al. 2010) on ‘diabetes out-patient cares before and after admission for diabetic foot complications’, indicated that there is a major decrease of amputation rates across a number of health-care services due to multidisciplinary foot clinic. The role of the multidisciplinary foot clinic in reducing the amputation rate worldwide in a variety of circumstances and economic resources has also been reported by Hopf (2008), Tudhope (2009) and Mclnnes (2011) emphasize that the multidisciplinary foot care team is the most effective way to provide patient education and manage foot problems. And from view point of Noble-Bell and Forbes (2008), the management of diabetes foot complications needs a multidisciplinary approach because diabetes foot problems are multifaceted.

Dargis et al. (1999) have shown that an institution of a multidisciplinary foot-care team and provision of appropriate footwear resulted in a 48% reduction of recurrent ulcers over 2 years study. A multidisciplinary foot-care team is expected to advise on footwear provision and get the opinions of patients’ satisfaction with footwear provision (Leese 2009). A fully functioning multidisciplinary team can bring a wide range of expertise that could have a dramatic impact on the patient foot-care and well–being. The patient should be motivated by the team to wear the recommended footwear, for it would be useless to provide bespoke footwear if the patient will never wear it or will not use it frequently (Tyrrell & Carter 2009).

1.2.4 The role of footwear in diabetics foot care.

In a life time, an average person takes between 8,000 and 10,000 steps a day, equal to walking 185,035 km or 115,000miles, more than four times around the earth. Levin (2008) and Vass (2006) argue that the case for comfortable footwear could not be better presented, if the person taking these steps has diabetes with neuropathy with loss of protective sensation, his or her feet could develop ulceration that could result in amputation.

There are different types of footwear for different purposes. In the case of using footwear for the management of diabetic foot problems, some patients can use retail footwear successfully whereas some would need shoes that are made on special or custom-made last (bespoke footwear). In some other cases, minor modifications to an existing stock footwear last and the footwear constructed on such last can meet the need of the patients. This type of footwear is referred to as modular orthopaedic footwear. But stock orthopaedic footwear (footwear made on special last, but available off-the-shelf) is another option that can be used to meet the need of diabetic patients (Tyrrell & Carter 2009).

Furthermore, some published research findings (Maciejewski 2004; Boulton & Jude 2004) support the belief that bad or inappropriate footwear causes ulceration. In fact, every second amputation in diabetic patients is preceded by an injury as a result of ill-fitting footwear (Reiber 1994). The authors mentioned above identified shoes as the precipitating cause in the majority of toe ulcers and a significant minority of lesions elsewhere on the foot. They stressed that there is an urgent need for well-designed studies on footwear in the primary as well as the secondary prevention of neuropathic foot ulceration. But the researchers concluded that whereas bad shoes cause ulcers, a major effort is required to demonstrate that good shoes do actually benefit high-risk patients.

Similarly, Nathan and Singh (2008) reported that wearing of proper diabetic footwear is a very important part of diabetic foot care and education. They stressed that in the near future, Diabetic Footwear Centres would be developed in Asia to design, fashion and manufacture diabetic footwear that is not only preventive, protective and therapeutic but footwear that is also aesthetic, low cost and culturally acceptable.

Specialist shoes that are designed in such a manner that the upper of the shoe and its lining are made of very thin soft kid leather, with broad deep toes could help to reduce pressure on the dorsum of clawed toes (Tovey & Moss 1986).

Nowadays it is increasingly recognized that growing number of older people and people with disability have special needs in product design and manufacture. To increase the use and usability of orthopaedic and diabetic shoes, Schoeffel (2003) and Michiel (2004) advocate that comprehensive evaluation studies should focus on all aspects of usability (usability is defined in the International Organization for Standardization (ISO) 9241-11 as ‘the extent to which a product can be used by specific users to achieve goals with effectiveness, efficiency, and satisfaction in a specified context of use’). Therefore, for any assistive technology to be effective, it is essential that they are actually used, to maximize the potential to contribute to positive health benefits (Netten et al. 2010). The need to review the system that provides prescribed footwear in the U. K. and identifies key areas that could influence patients’ satisfaction has since been noted by Williams and Meacher (2001). They found out that patients’ dissatisfaction with prescribed footwear results in low usage and that the cause is the system that provides it. The National Health Service (NHS) in the U. K. provides prescription footwear free for patients with different kinds of disability and foot pathology. When the footwear is effective, the benefits to the patients are improved mobility, comfort, protection and generally improved well-being.

Boulton and Jude (2004) explain that the neuropathic foot is insensitive (due to sensory neuropathic), dry (due to sympathetic denervation) and warm (well perfused in the absence of co- existing peripheral vascular disease. Areas of high pressure usually develop with weight bearing due to alterations in foot anatomy.

Shoes are seen (Vernon 2007) as an essential part of comprehensive foot care and is likely to be regarded as an important consideration in the clinical management of many foot disorders. Pezza (2011 P. 151) commenting on the importance of shoes in podiatric practice, pointed out that ‘majority of the patients that are treated everyday have two feet’ and that they all need shoes. He further explains that majority of the patients have foot problems because of improper footgear or as a result of wearing the wrong size or width. Some of them could have prevented major complications such as diabetic ulceration or amputation if they had been wearing the right shoes all along.

Previous studies (Rith-Najarian 2000; Chantelau & Haage1994) indicate that regular use of therapeutic footwear is an effective means of protecting the high-risk foot from injury, and has been associated with an approximately 50% reduction in ulceration rates. It is important to point out that the underlying mechanism of therapeutic footwear is stabilization and cushioning of the foot to reduce pressure and frictional forces that lead to ulceration, tissue injury, etc. For an effective use of this intervention, physicians require knowledge of the mechanics of the different types of shoes, their prescription, dispensing, and precautions, and also how to promote patient use of the shoes. Guidelines for the prevention of diabetic ulcers (Steed et al. 2008) indicate that protective footwear should be prescribed to any patient at risk for ulceration (that is, significant arterial insufficiency, significant neuropathy, or previous amputation).

Therapeutic footwear can have a cushioning effect or redistribute the pressures that develop under the foot and can be used by patients to reduce the risk of ulceration by relieving mechanical pressure on the foot (Bus 2011; Sarnow et al. 1994). Also, they can reduce re-ulceration rates by half, at least in the short-term. Those with neuropathy are advised to avoid loose fitting footwear such as slippers and rubber boots, and to also avoid open shoes like sandals and flip-flops in order to avoid some substances like sand entering the shoes and then act as an abrasive (Leese 2009). It appears that the therapeutic effect of good footwear is extremely valuable. Some researchers particularly said that;

> "Footwear can be an extremely valuable therapy, providing patients with a means of relieving pain and discomfort, optimizing gait patterns, increasing mobility levels and improving quality of life"
>
> Tyrrell and Carter (2009, p.246).

Therefore, it is strongly believed that the use of shoes to protect the feet should be promoted through educational package. An investigation (Boer & Seydel 1998) carried out on prescription footwear showed that there is significant need of education about prescription footwear among health practitioners. However, protective or appropriate shoes for people suffering with foot problems are often not readily available in remote communities (Watson, et al. 2001).

1.3 Motivation

The author was motivated to carry out a study on diabetes footwear because of the following reasons:

- Diabetes patients' satisfaction with prescribed footwear is reported to be low (Waaijman et. al. 2013; Williams & Meacher 2001).

- It is understood from the literature (Williams & Nester 2006) that the current stock footwear design has been developed through technological advancements, results of research on clinical need and perspectives. However, in addition to these, the design and manufacture of diabetes footwear based on an understanding of patients' expectations and perceptions of footwear is not often considered.

- Currently, 285 million people are affected with diabetes worldwide and the number is expected to grow to 438 million by 2030. And the largest age group currently affected by diabetes is between 40-59 years old (World Health Organization 2010; International Diabetes Federation 2009; and World Footwear 2008). It therefore means that diabetic footwear has become a growth market.

- Foot problems are a threat to everyone with diabetes (Bakker 2008; Edmonds1987). Their foot problems often required prolonged and costly hospital stays and eventually leading to amputation of a toe, foot, or the lower limb completely. And according to Leung and Wong (2008), for patients with special need in their footwear that cannot be answered by commercial shoe, input from a professional is needed. This is important as improper footwear has been shown to be a common culprit for causing foot ulcer in diabetes.

- In addition, footwear can prevent or increase foot ulceration (Cavangh 2008; Nathan 2008; Janeberg & Donofrio 2008; Maciejewsi et al. 2004). Also, Boulton and Jude (2004) point out that footwear is probably one of the main reasons for the lack of progress in reducing foot ulceration and amputation rates among the diabetes population and many amputations can be averted by wearing appropriate shoes (Caselli 2011). Furthermore, Torreguitart (2009) pointed out that the use of inappropriate footwear is the most common cause of foot ulcers. Indeed, the role of footwear in the management of diabetic foot problems requires urgent attention because data from investigators (Reiber 1994; Edmonds et al. 1986; Apelqvis et al. 1993) show that 39-76% amputations in diabetic population were initiated by ill-fitting footwear.

- There is paucity of research in the area of footwear in diabetes (Ogrin 2007; Cavanagh 2004) and a comprehensive concept of technical requirements for diabetes footwear is lacking (Dahmen et al. 2001). Therefore, there is a great challenge for footwear designers and health professionals to work together to solve the problem.

- Health professionals advocate for a multidisciplinary approach to management of diabetics and its complications (Tyrrell & Carter 2009; Pedrisa 2006; Edmonds et al. 2006; Connor1987; Nigg1986; Edmonds, & Foster 2005). Therefore, those in the field of footwear design have a stake in solving this problem faced by every society in the world today, and can make significant contributions to knowledge that could provide solution to this global challenge.

- Most research on designing footwear for people has concentrated on comparing different shoes or materials rather than comparing the basic physical characteristics of the materials that are used (Goonetillete 2003). It is therefore believe that there is wide range of materials with variety of properties that could be explored to make suitable footwear for numerous foot conditions.

- The need for research to collect data on diabetic foot complications and the appropriate preventative measures have been pointed out (International Diabetes Federation (IDF) and International Working Group on the Diabetic Foot (IWGDF), (2005). Therefore, Inputs from footwear designers are required to solve or at least reduce diabetic foot problems by designing appropriate footwear.

The above mentioned issues captured my attention and provided me with areas for this research. A reflection on my M.Sc. dissertation (Tagang 2010) and discussions with my major supervisor after my M. Sc. Programme, further strengthens my desire to explore this problem area. More importantly, the focus of this present work is to discover the potential solutions that will contribute to providing or improving diabetes patients' foot health condition in Nigeria through the provision of appropriate footwear. I believe this work has the potential for contributing to positive foot health benefits for people suffering with diabetes.

1.4.0 Research Aim and Objectives

1.4.1 Main Aim

To formulate a framework that would identify appropriate materials and suitable designs for diabetic footwear particularly for people suffering with diabetes in Nigeria.

1.4.2 Main Objectives.

- To search and review the relevant literature regarding the subject area.
- To source for relevant information from diabetic patients using questionnaire survey.
- To source for information from health professionals on the important factors to be considered for designing diabetes footwear.
- To study appropriate footwear materials and design(s) for people suffering with diabetes.
- To develop appropriate footwear design(s) solution for people living with diabetes particularly in Nigeria.
- To identify areas for further research.

1.5.0 Scope of the Research

This study focuses on the role of footwear in the management of diabetic foot problems, appropriate footwear materials and design(s) for people suffering with diabetes particularly in Nigeria and other developing countries.

1.5.1 Research Structure.

The research structure presented below (fig. 1.2) was used to carry out this research. The PhD journey started with a critical thinking of the research area/ topic, formulation of the aim/ objectives and the research methodology. Basically, the research structure is categorized into three data sets as follows:

- Data set involving research participants: This includes information gathered through the pilot study, questionnaire and interview surveys, foot measurement and prototypes assessment.

- Experimental analysis data set: This set of data was based on shoe upper materials laboratory analysis.

- Data set based on previous literature: Information gathered from the background study and literature review constituted this data set.

In summary, the structure for this study was developed based on established secondary and primary research methods identified in previous literature. For effective gathering of information and validation, it was agreed that relevant and related data should be collected both from diabetic patients and health care providers. Consequently, structured interviews and questionnaire were developed for collection of data from diabetic patients and medical doctors respectively. However, to complement the findings from the two methods mentioned above, two additional studies (footwear materials analysis and foot measurement) were designed. It was anticipated that the experimental analysis would provide information about suitable materials for diabetic footwear manufacture; whereas the foot measurement would provide data on foot dimensions that could help to determine proper footwear fitting.

In addition, the research structure was designed in such a way that data collected from the secondary and primary research would be analysed, interpreted and used to make trial prototypes that were assessed in real life situation (see chapter 7). The structure also provided a section for general discussion on the key findings from the study. This section gives clear understanding of all the issues and ideas that were discovered from each aspect of the study by linking or comparing them one to another. And finally, conclusion and recommendations for further research were outlined based on the outcomes of both the primary and secondary research and the assessment of the trial prototypes.

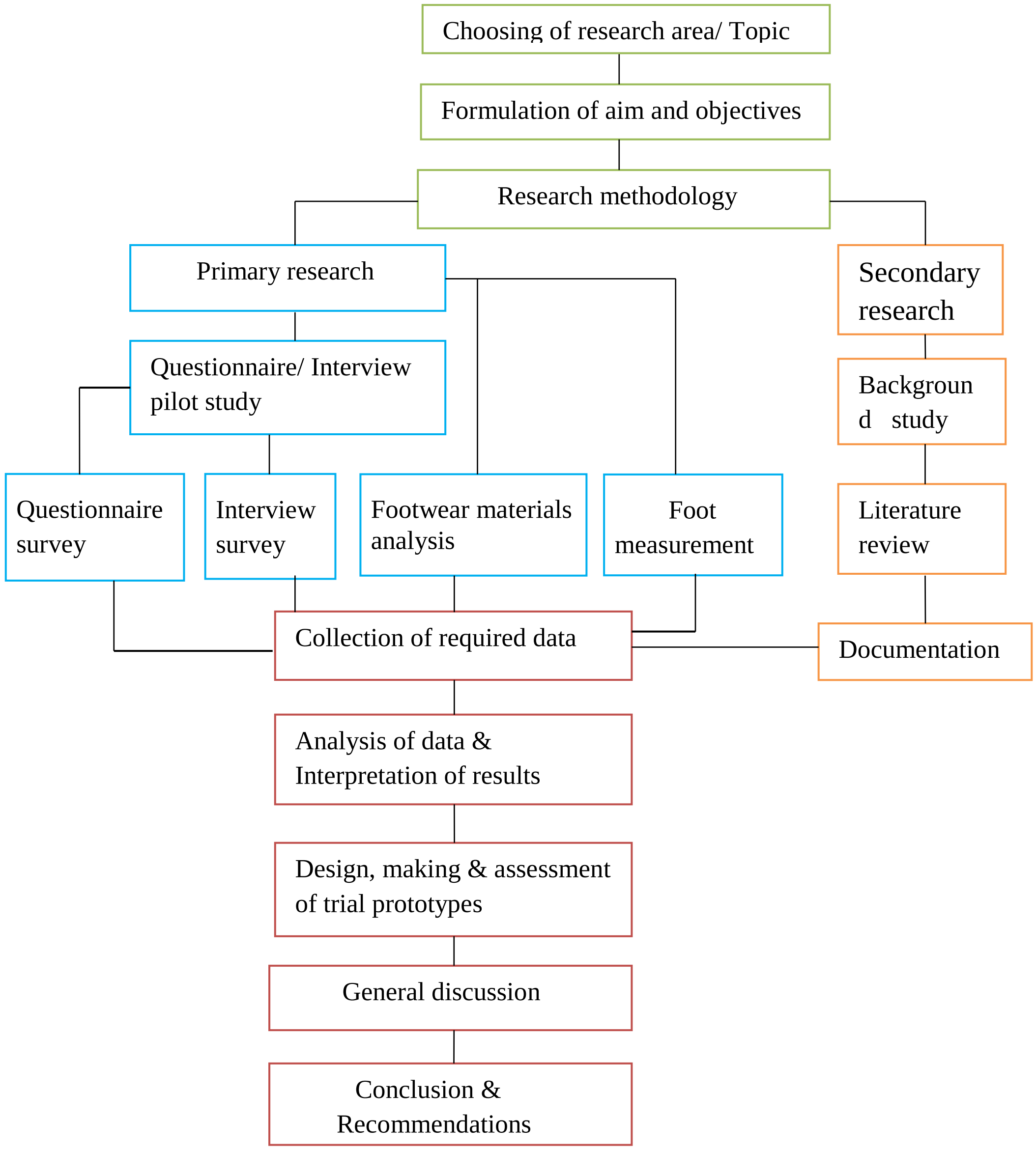


Fig.1.2 Research structure.

1.5.2 The structure of the thesis.

Figure 1.3 gives the structure of the thesis. It is grouped into four sections namely; (1) introduction and review of the relevant literature, (2) data collection and presentation of results, (3) prototyping and design framework, and (4) general discussion and conclusion.

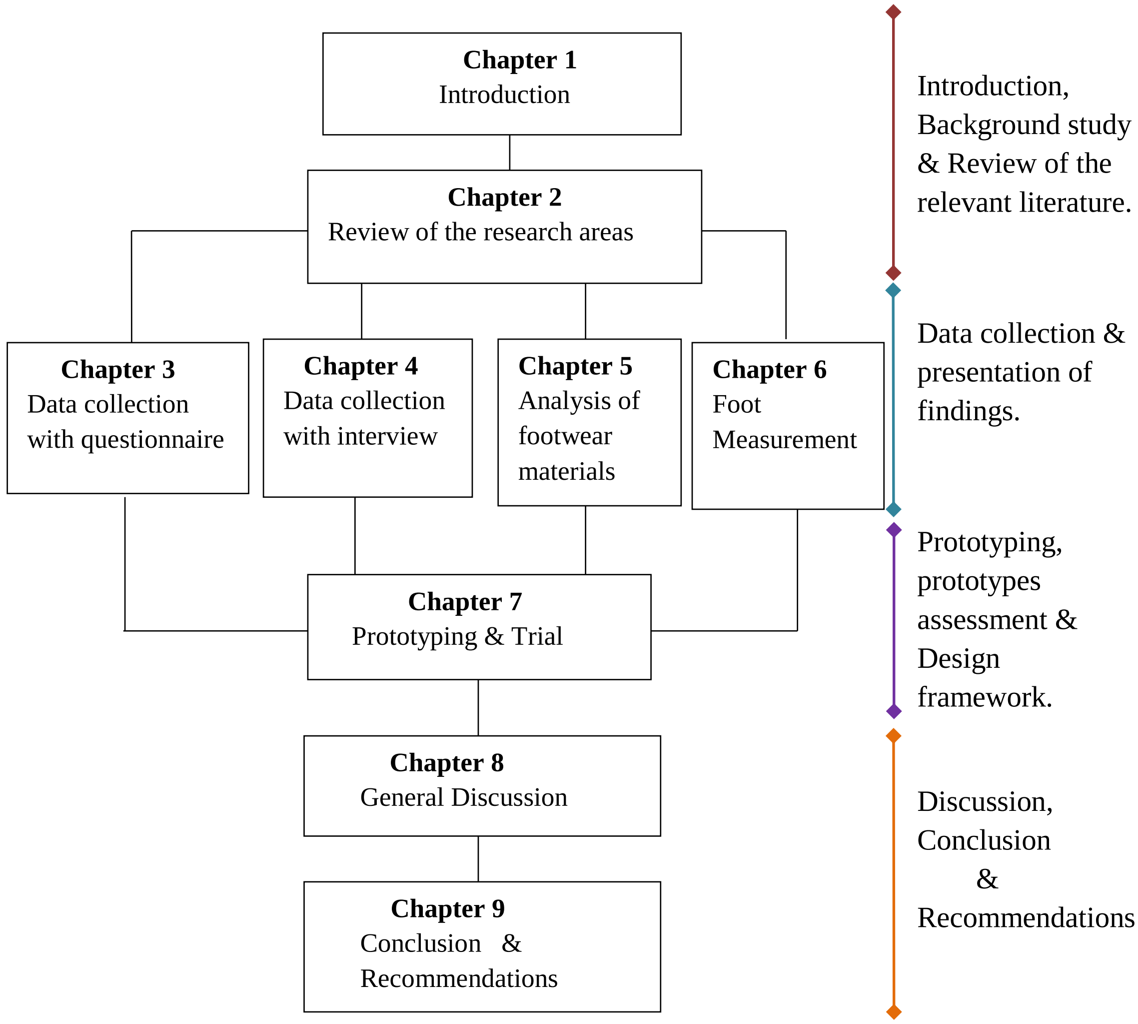


Fig.1.3 Structure of the thesis.

1.6.0 Methodology

Research methodology is the tools for doing research and obtaining useful information. Clough and Nutbrown (2007) define research as "the investigation of an idea, subject or topic for a purpose. It enables the research to extend knowledge or explore theory. It offers the opportunity to investigate an area of interest from a particular perspective". And according to Adams and Schvaneveldt (1985, p. 50), "Research methodology applies a systematic approach to problem solving and data collection to ensure that one has useful data, that the results can be understood by others, and that the procedures can be carried out by someone else at a later time. With data gathered in research, we can explain, predict, describe, and eventually relate current studies with other research".

Key methodological components that cut across quantitative and qualitative methodologies were used in this study (see sub-sections 3.4, 4.4, 5.4 & 6.4).

This research was undertaken based on established research processes as shown in figure1.4 Research process in this sense is seen as cyclical. The process is shown as going through a number of cycles, the outcome of each one influencing upon the way in which successive cycles are approached.

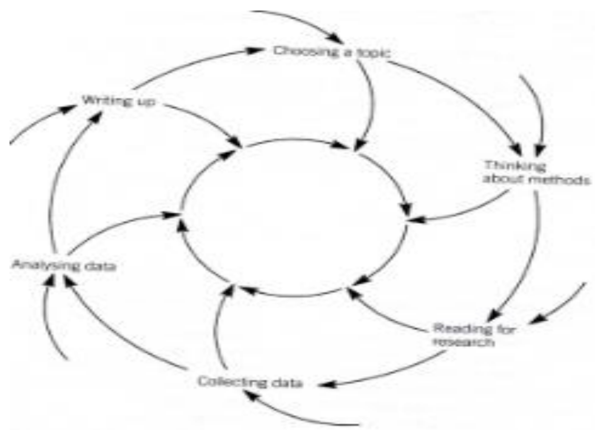


Fig.1.4 The research spiral (Blaxter et al. 2010. p. 9).

There are two main approaches for gathering information or data in any structured research work. The first approach is from secondary sources, whereas sources used in the second approach are called primary sources (Ranjit 1999). The two methods are briefly explained below.

1.6.1 Secondary Research

This information and/ or data are gathered from second hand sources: reference books, journals, and government statistics, internet, etc, which supply information on wide range of issues (Wall et al. 1996).

The published literature was used by the author in order to:

- provide an academic basis to the research carried out,
- to clarify ideas and findings,
- to find data and research methods to be adopted.

Using the published literature is a core part of the academic communication process. It connects the work someone has done to the great scholarly chain of knowledge, and in more immediate terms it demonstrates someone understanding and puts the work he has done in a wider context (Department of Library Services, De Montfort University, Leicester). Therefore, the author used secondary research tool to put his work in the right perspective (see chapter 2).

1.6.2 Primary research

The aim of the primary research was to gather first hand information on different aspects of the subject investigated through interview survey, questionnaires survey and laboratory analysis of footwear materials.

There are various vehicles that are used for collecting primary research data which can broadly be categorised into two types namely: qualitative and quantitative. Qualitative method of research seeks out the 'why' not the 'how' of its topic through the analysis of unstructured information-things like interview transcripts, e-mail, etc. It does not just rely on statistics or numbers, which are the domain of quantitative method of research (QSR International, 2007). On the other hand, quantitative research is used to measure the 'how' of its topic through analysis. This type of research is very effective when measuring for example, how many people feel, think, or act in a particular way. Quantitative surveys tend to include large samples, for example structured questionnaires can be used incorporating mainly closed questions. But closed questions have a limited set of responses (Research Portals 2009).

In this project, both methods of research mentioned above were explored to obtain the required data (see fig. 1.5).

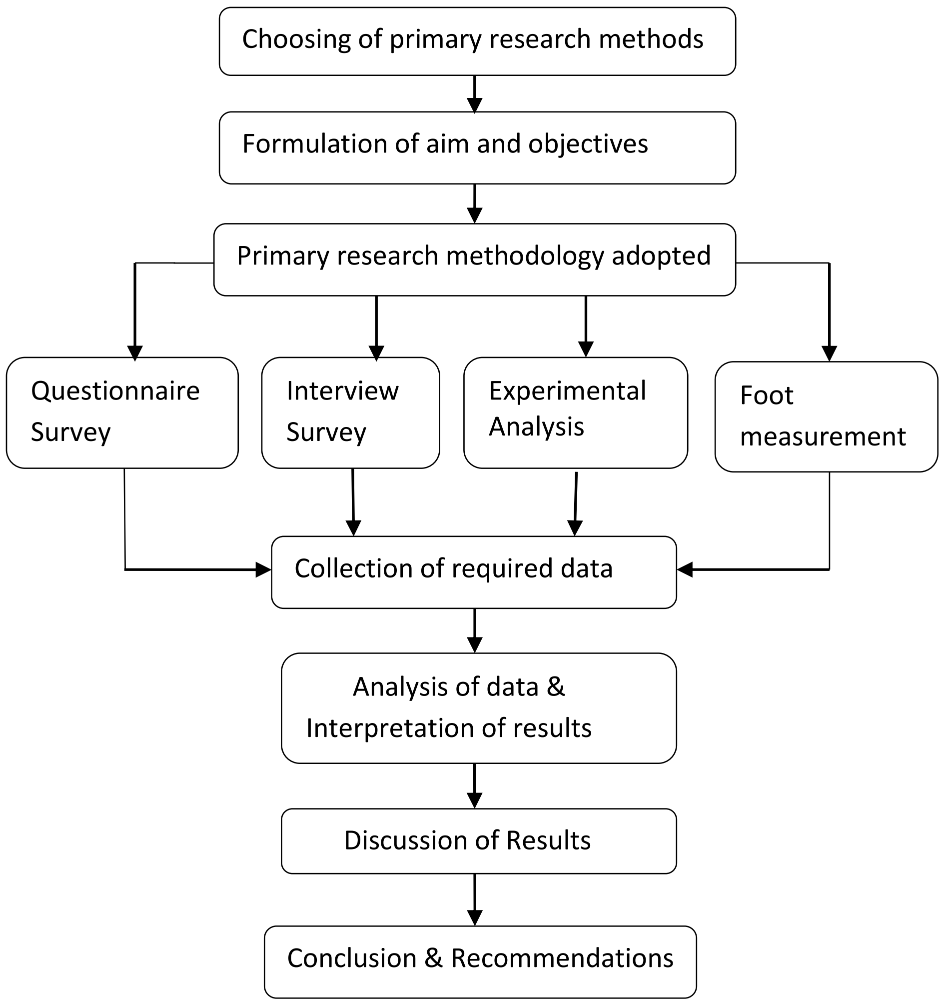


Fig. 1.5 Primary research structure.

The researcher utilized quantitative research method by designing a detailed questionnaire which included personal profile of the respondents, Information on diabetes foot care and foot problems, foot problems developed as a result of using inappropriate footwear, and footwear fitting/ features. The required information was gathered from people living with diabetics from a developing society, Nigeria. The outcome and explanation of the data obtained from the questionnaire survey are provided in chapter 3.

The researcher equally used interview survey to achieve the aim and objectives of his study. According to Patton (1980), interview is a process of obtaining information via questioning conducted face-to-face or over a telephone. The researcher interview medical doctors and their views on key aspects of the research are presented in chapter 4.

In addition to the questionnaire and interview approach, it was also necessary to carry out experimental analysis of footwear material in order to understand materials that would be more suitable for making the product.

These research methods were used because a range of research methods would allow the development of multiple viewpoints; it also allows inductive and deductive reasoning, ensuring that all aspects of the research question are being investigated.

1.7.0 Research and Time Management.

1.7.1 Research Management.

The negotiated project was the individual responsibility to carry out careful planning of the research activities. First and foremost, the project title, aim and objectives were set out after negotiating with the supervisors (see sub-section 1.4). To achieve the aim and objectives of the project, the project was divided into several main sections. The main sections were further sub-divided into small research activities in order to get a clear research structure (see fig. 1.2). A list of research activities (see appendix I) was then formulated from the research framework. After establishing the research activities, a project plan in the form of a chart (See appendix II) was drawn to achieve the research aim and objectives. In addition, progress reports (at least monthly) of discussions held between the student and the supervisors was kept as evidence of regular progress meetings via "MyDmu" throughout the period of the study. An example of the researcher's progress report is given as appendix III.

The literature search, citation and review (secondary research) activities were based on study of books, journals, magazines and articles from internet sources. Most of the articles used for the research were collected from the University's Library (Kimberlin Library). Information from the secondary research was explored to meet the objectives of the project.

The primary research was carried out mainly in Nigeria. It was difficult to stay on schedule with some of the activities, such as interview and questionnaire surveys. However, regular discussions with the supervisors helped the researcher to manage the project within the overall time scheduled.

1.7.2 Time Management

Time management is defined "as systematic, priority-based structuring of time allocation and distribution among competing demands" (The Business Dictionary 2010). To help manage time and to be able to complete the project on the target time, the main research areas were identified and split up to develop a monthly plan (and some tasks were further broke down into weekly plan). From the research breakdown, a Gantt chart (look at appendix II) was drawn up to demonstrate the research activities against the time schedule. The Gantt chart was a useful tool for analyzing and planning of all the research tasks. Using the tools provided by 'Mind Tools' (2010), the author identified the activities that were dependent (or sequential) on other activities being completed first. These dependent (see appendix I) activities were completed in a sequence, with each stage being more-or-less completed before the following activity began. Other activities that were not dependent (parallel tasks) on completion of any other tasks were also identified. These tasks were done at any time before or after particular stage were reached. The Gantt chart was drawn by following the following steps:

a. All the project activities were listed and for each task, the estimated length of time required to complete the task was recorded.
b. A chart was used to indicate the months (s) through to completion.
c. The tasks were plotted onto a chart, showing the starting date or month and the month of completing each task.

1.8 Chapter Summary

This chapter gives the general introduction, the background of the study and the structure of the research/ thesis. The background has shown that diabetes often leads to foot problems and that the manifestations of the foot problems often require specially designed or adapted footwear. The author was motivated to carry out this work based on the fact that foot problems are a threat to everyone with diabetes and that footwear can prevent or increase foot ulceration or problems. Related research work conducted by individuals and group of researchers in this area have shown that a comprehensive conceptual approach for the management of the various aspects of diabetic foot problems is still lacking. Therefore, the author aimed in this study to find out the possible design solution for diabetes footwear particularly for people suffering with the disease in less developed societies like Nigeria. Secondary research (literature review) and primary research (questionnaire and interview surveys, experimental analysis and foot measurement) were the main research tools used to conduct the study and a Gantt chart was used to successfully manage the project.

The next chapter is a critical review of the literature of the research area; that is diabetes and diabetes foot complications, the role of footwear in diabetes foot management, footwear materials and design, etc.

Chapter 2: Literature Review of Research Areas

2.1. Introduction

Literature reviews according to Gregorio (2000) are a common feature of all dissertations, regardless of discipline or subject matter. The main goal to achieve in literature review is to gather information or to develop a knowledge and understanding about a particular topic from many different but relevant sources on previous work or activity and in regard to the topic been searched. The information can be used for a variety of purposes, including identifying of gaps in research literature, to uncovers all relevant knowledge and research method related to the topic, linking ideas from different articles, identifying contradictions in agreement, comparing dissimilarities in articles, building one's own argument and identifying areas for further study (Gregorio 2000; Timmins & Mccabe 2005; Blaxter et al. 2006).

Furthermore, Philips and Pugh (2005) point out that literature review allows the researcher to demonstrate that he has professional grasp of the background theory of the subject. It also enables the researcher to evaluate the contributions of others, and to identify areas of theoretical and empirical weakness.

Based on `this, the literature review helped the researcher to have an appraisal of the current developments in diabetes footwear and gave him an insight on what to focus on in this present work. In other words, the literature review enabled the author to develop a knowledge and understanding of the previous works in regard to the research topic.

Timmins and Mccabe (2005) suggested that a systematic, organized search of the literature that uses wide range and available resources effectively is more likely to produce quality work. Therefore, to develop a meaningful discussion and argument on the research topic, the researcher carried out the task of searching, selecting, and reviewing of the relevant literature throughout the period of the study to inform and guide each stage of the research process.

Once the research area and key words were identified, a literature searching map (see fig. 2.1) was designed before the process of searching, selecting and reviewing of the literature started. The map was used to obtained relevant information from books, journals, technical bulletins, survey reports, conference papers, etc.

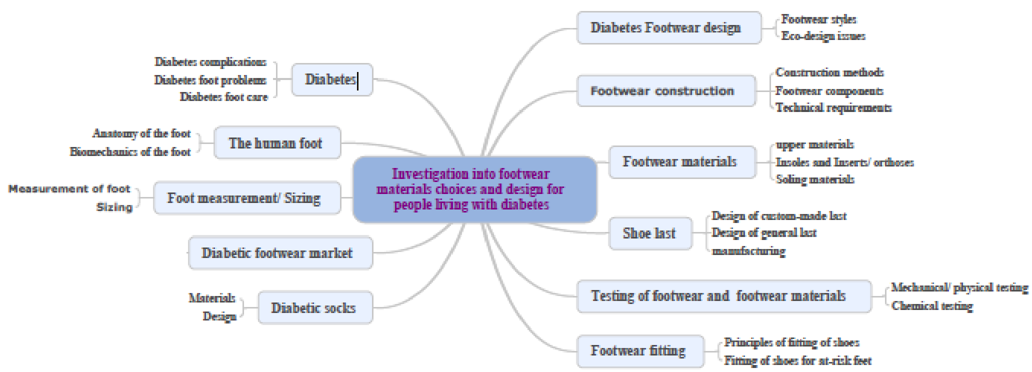


Fig. 2.1 Literature Searching Plan (Mind-map)

This review or secondary research was based on extensive and comprehensive review of the relevant and recently published work using different data bases such as the ones outlined below.

- Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- Academic Search Premier (EBCOS)
- Nursing, Midwifery and Allied Health Professions (NMAP) http://namp.ac.uk
- Health on the Net Foundation. www.hon.ch/
- Medical Database-Medline/ Pubmed.
- The electronic Theses Online Service (EThOS).

Immediately the literature search begun, the researcher organized and managed all materials or articles in a logical and systematic way for analysis and integration in the review using Mendeley Desktop reference management software (see fig. 2.1).

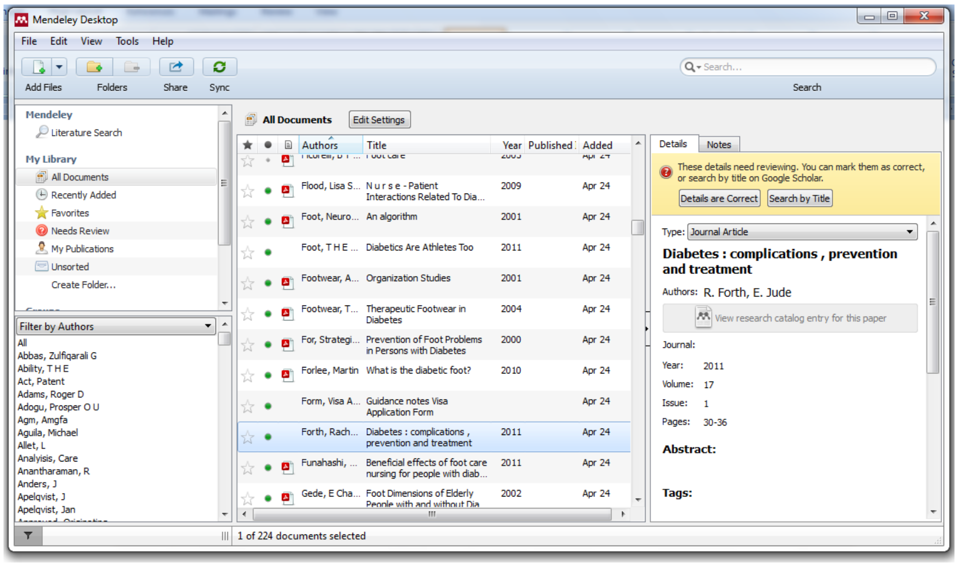


Fig. 2.2 Screen clipping of Mendeley Desktop reference management software (Screen clipping taken: 7/25/2013, 6:13 PM).

2.2.0 Aim/ Objectives of this Chapter.

2.2.1 Aim

To review the relevant literature in order to discover what other researchers have done concerning this subject matter and their opinion or suggestions for further work on diabetes footwear and to use findings and suggestions to develop this present work.

2.2.2 Objectives

1. To plan when, where and what information to Search.
2. To collect books, journal articles and other sources of Information.
3. To review and analyze the relevant literature.
4. To cite the literature and develop conclusion.

2.3.0 Diabetes

Diabetes is explained as a disease that affects a person's ability to control the glucose levels in his blood either because the person's body does not produce sufficient insulin by the pancreas or because the person cells are not able to respond to insulin. And Insulin is the hormone that regulates the uptake of glucose from the blood into most cells, but mainly muscles and fat cells (Sharp 2011; Forth 2011). According to Faris (1982) it is a disease in which water does not remain or stay long in the body. The features/ symptoms of the disease include weight loss, thirst, physical inactivity and polyuria (Faris 1982; WHO 2006).

The disease is classified into two types: Type 1 and Type 2. In type 1 diabetes no insulin is produced by the beta cells of the pancreas and is most commonly diagnosed before the age of 40 years (Nazarko 2011; Williams & Pickup 2005; Rotchford & Rotchford 2002). Type 1 diabetes affects 10 to 15% of people with diabetes and there is a complete lack of insulin production (McIntosh 2006; WHO 2006). On the other hand, Type 2 diabetes (Brown 2009) is characterized by insufficient insulin production or the body's ineffective use of insulin as a result of beta cell failure, and insulin resistance. It is commonly found among older people aged over 40 years but is becoming more common in younger people. This type of diabetes affects 85 to 90% of people with diabetes. In another classification of the disease, Faris (1982) pointed out that there are two forms of diabetes namely; diabetes insipidus (or spurious) in which there is no sugar in the urine or diabetes mellitus (or vera) in which the urine contained sugar. It has been reported that type 1 diabetes is not common in Africa but fatal, whereas type 2 diabetes in the continent is arising in epidemic proportions (Beran & Yudkin 2006).

There has been a dramatic increase in recent years of people worldwide developing diabetes. While the disease can be controlled through medication and diet, complications can still arise. One of these is ulcerated feet caused by pressure points inside the shoe (World Footwear 2006). Perry (2002) has reported that incidence of diabetes increases with age and that the risk of developing the condition differs according to ethnic group: Asian people and black people being at higher risk of developing the disease than the general population or any other ethnic group in the world. But the cases of diabetes are rising worldwide (Bakker 2005). The report given by Patel (2003) and World health Organization (2011) show that, in 1935, 15 million people had diabetes throughout the world, in 2004,150 million had diabetes, and it is predicted that this will rise to 366 million by 2030.

2.3.1 Diabetes Complications

It has been reported that complications in diabetes can be acute or chronic (Forth & Edward 2010) and that the condition reduces life expectancy by 10-15 years (Hill 2011; Nazarko 2011). The disease is associated with many complications (Ahmed 2005; Diabetes UK 2009a, Edo, et al. 2013) that affect several organs of the body, including the eyes (retinopathy), heart (cardiovascular disease), kidneys (nephropathy) and the nervous system (neuropathy). But the foot is particularly affected because of how easily nerve damage can occur there without immediate detection. Loss of blood flow, and subsequently numbness to the extremities means that infection may go entirely unnoticed until it spreads beyond repairs (World Footwear, 2008). The condition can also have significant effect on wound healing and management (Johnson and Rogers, 2011). According to Przybylski (2010), the current global epidemic of the disease (type 2 in particular) has led to an accompanying increase in both foot ulceration and amputations, which is regarded as significant health problems to populations worldwide. Diabetic foot problems incur substantial economic burden for society, patients and families worldwide (Ivy et al. 2008). Diabetic neuropathy and its different categories are outlined as follows:

Diabetic Neuropathy

Neuropathy is described as damage to nerves (Diabetes UK, 2012). It is understood that high blood glucose levels can damage the body's nerves, weakening their ability to transmit signals. It can also damage the blood vessels that carry oxygen and nutrients to the nerves. Data from U. S. National Diabetes Fact Sheet (2011) indicate that about 60% to 70% of people with diabetes in America have mild to severe forms of nervous system damage. The data further show that almost 30% of people with diabetes aged 40 years or older have impaired sensation in the feet (that is, at least one area that lacks feeling). And severe forms of diabetic nerve disease are seen as a major contributing cause of lower-extremity amputations. Chan (2012) in his work titled 'foot care in diabetes' states that approximately 42% of all diabetes patients will develop neuropathy within 20 years of diagnosis.

Diabetes complications can be divided into two: Macrovascular defects and microvascular defects. Macrovascular complications include stroke, cardiovascular disease, and peripheral vascular disease. These are said to be the major cause of mortality for people living with type 2 diabetes mellitus (Casey 2011). Krentz and Bailey (2001) explain that microvascular complications arising from diabetes include neuropathies, nephropathy, retinopathy and encephalopathies. These may cause foot ulceration, visual impairment, end stage renal failure, and non-traumatic amputation. Neuropathic foot ulcers are common and estimated to affect 15% of all diabetic individuals during their lifetime (Pendsey, 2010).

There are different types of neuropathy (Diabetes UK, 2009a) namely;

1. **Sensory neuropathy:** This affects mainly the nerves that carry messages from the skin, muscles and bones to the brain. It is considered as the most common type of neuropathy and mainly occurs in the feet and legs, but can also occur in the arms and hands. This type of neuropathy can lead to a loss of feeling and a failure to sense pain. It is characterized with numbness and extreme sensitivity to touch.

This type of neuropathy mainly affects the lower limbs and the first symptom that could be recognized is often an ulcer (Nather et al. 2011; Pozo 2009).

2. **Motor neuropathy:** This form of neuropathy is not common and can affect the eyes and muscles of the legs and feet. It causes muscles weakness and sometime painful. This condition can affect the nerves that supply the muscles in the foot which can lead to the development of foot deformities.

3. **Autonomic neuropathy:** This type of neuropathy affects mainly the nerves that control the automatic workings of the body. The parts of the body usually affected include the sexual organs in both males and females (causing erectile dysfunction and vaginal dryness), stomach, intestine, sweat glands and sometimes the heart.

Patients with neuropathic complications are advised (Torreguitart 2009; Meadows 2006) to follow some guidelines when choosing footwear:

- Footwear should not be too tight and should have Velcro or shoelaces so that it can be adapted to the foot.
- Footwear should be purchased in the evening when the foot is most edematous.
- The sole should be made of non-slip rubber.
- The heel should be between 2cm and 3cm high and have a wide base to avoid instability.
- Leather should be the material of choice because it is flexible and allows feet to breathe.

Sharma and Kerri (2000) recommended that people that have neuropathy to be more vigilant to prevent injury because they are more likely to damage their feet. For example, in sensory neuropathy, patients do not feel pain or discomfort which can lead or contribute to the development of charcot's joint-damaged, swollen and deformed joints as a result of repeated minor injuries.

2.3.2 Diabetes foot complications

There are many complications that affects people with diabetes (see the previous sub-section), but none are more devastating than those involving the foot and the number of foot problems is escalating due to the increasing diabetic population who are living long enough to develop foot complication (Levin & O'Neal 2008; White & Mulley 1989). Research has shown that as the number of people with diabetes increases, more and more foot problems will be witnessed. For example, in the U.S there are 21 million diabetic persons with 42 million diabetic feet and 210 million diabetic toes and despite the many treatment modalities available today, the number of amputations, including toes to midthigh, keep increasing (Embil 2009; Bus 2008; Levin & O'Neal 2008).

The foot is the main site for ulceration for patients with peripheral neuropathy, because the loss of feeling cause by neuropathy usually starts at the extremities, in the hands and feet, and because of repetitive stresses and constant weight on the feet during walking (Kennedy 2010). It has been shown (Benn et al. 2005) majority of ulcers in neuropathic subjects occur in the forefoot, so forefoot off-loading is particularly important because forefoot pressure is higher than rear foot pressure. Therefore, particular attention needs to be paid to any wounds or lesions that may begin to develop there.

Foot deformity usually leads to bony prominences which often cause ulceration (see fig. 2.3) as a result of high mechanical pressure on the overlying skin due to the absence of protective pain sensation and when shoes are unsuitable. Common deformities that could be noted in a diabetic foot are claw toes, hallux valgus, hallux rigidus, hammer toe, charcot foot and nail deformities (Edmonds 2006). According to Bakker and Foster, 85% of amputations are preceded by an ulcer and that there is an amputation every 30 seconds throughout the world.

A b C d

Fig. 2.3. Different Diabetic foot conditions. Image (b) available at: http://commons.wikimedia.org/wiki/File:Charcot_arthropathy_clinical_examination.jpg (Accessed on 01/08/13).

Recently, Katreddy and other researchers (2010) presented the outcome of a study they carried out on “In Patients with Diabetes: the scale of foot problems” during the 13th Marvern Diabetic Foot Conference, Worcester, U.K. Their research results have shown that significant percentage (19%) of diabetic patients had active foot problems that required specialist advice. Their study also demonstrates the fact that significant percentage of diabetic inpatients has high risk and active foot problems. They advocate for the adoption of the campaign on ‘Putting Feet First’ in the U.K in order to improve quality of life of people living with diabetes. Because of the fact that education and awareness play significant role in achieving the aim of designing special footwear for the diabetic foot, the researcher would investigate diabetic patients’ knowledge of foot care and, or the role of footwear in the management of their feet problems.

Foot complications as a result of diabetes will usually result in extensive hospitalization, disfiguring surgery, lifetime disability and diminished quality of life (Morris 1998). It is estimated that 40 to 60% of all non-traumatic amputations on the lower limb are now carried out for diabetic foot problems (Nathan 2008). And Hill (2011) reported that diabetic foot problems are a major cost to the NHS which has a significant impact on the lives of the people with the disease. According to Bakker (2006), the diabetic foot is a significant economic problem, particularly when amputation results in prolonged hospitalization, rehabilitation, and an increased need for home care and social services. Actually, foot complications account for more hospital admissions than any other diabetic complications (Forlee 2010). Therefore, Jeffcoate and his colleagues (2008) advocate that treatment options for diabetic foot complications that would result in cost effectiveness for both healthcare providers and the patient should be sought and promoted.

2.3.3 Diabetes Foot Care: the role of footwear

People have long worn footwear for a number of obvious reasons, including serving as protection from the environment (preventing the feet from injuries from sharp objects), as an aid to functioning in various sports and work endeavors, as an aspect of fashion or status, and to assist in ambulation when there is impairment to normal gait. In order to utilize footwear to protect the foot from injury and improve ambulation, health practitioners must be thoroughly familiar with the many functions that shoes can serve, the proper method of fitting shoes (see sub-section 2.11), the factors that go into determining the patient's footwear needs, and the types of specialized shoes and shoe modifications that are available to fill these needs (Rome et al. 2013; Caselli 2011; Broussard 2002).

In addition, a group of researchers (Maciejewski et al. 2002) studied the preference of footwear by people living with diabetes and a history of foot ulcer from two large Western Washington state healthcare organizations. They carried out their study base on clinical trial of footwear, self-reported information on footwear preferences, use, and cost were obtained from people with diabetes and a prior healed foot ulcer. They recommended that healthcare professionals should always give diabetic patients information on good footwear choices to enable them to always use appropriate shoes and to avoid ‘dangerous shoes’. Equally, this current research would look at the features of footwear that should be emphasized or prescribed for diabetic patients (particularly in the developing countries) but the present study is not based on clinical trial of footwear.

On the issue of meeting the needs of the diabetic patients, Moore (2007 p.107) states that:

> “The bottom line is that diabetic patients will have many lower extremity needs over the course of their lives. From care, diabetic footwear, hospital management, off-loading devices, vascular assessment, to neurological assessment, education, nutritional education, physical therapy; and the list goes on and on’’.

However of the many complications that affect people with diabetes, none are more devastating than those involving the foot (Levin & O’neals 2008), hence the need to look at the various options of treatment and prevention available for effective care of the diabetic foot in more details. According to some researchers (Munro & Steele 1998; Haspel 2007; Wright 2010; Jude 2011), foot complications may be prevented and minimized with early diagnosis, good patient education, effective treatment and the use of quality footwear to off-load areas of the feet which have ulcerated or potentially will ulcerate.

Ulbrecht and Cavanagh (2008) conclude on this issue of diabetic foot care that footwear can both cause and prevent foot injury. Therefore, they advocate that practitioners dealing or treating people with diabetes must understand the principles and practice of comprehensive foot care, including the prescription of appropriate footwear. Also, in primary diabetes care, evaluation of footwear and insoles by clinicians should be a standard part of the lower-extremity examination. They further stressed that people suffering with diabetes must understand that wearing prescribed footwear falls into the same category as taking medication-something that is indispensable for preserving their health.

Fig. 2.4 Examples of diabetic footwear. Available from: http://www.google.co.uk/images?q=diabetes+footwear&um=1

The National Institutes of Health, U.S.A in 2002 conducted a clinical trial of footwear in patients with diabetes which was sponsored by the Department of Veterans Affairs. Their study reveals that lower extremity ulcers preceded 84% of diabetic amputations. They lamented that the efficacy of footwear in preventing ulcers and amputations in the high-risk diabetic population has received limited experimental investigation even though nearly half of the events that lead to ulcer and amputations in the high-risk diabetic population were initiated by ill-fit footwear. Also, Boulton (2008), Knowles and Boulton (1996) affirmed that footwear is probably one of the major reasons for lack of progress in reducing foot ulceration and amputation rates. These researchers point out that appropriate footwear plays pivoted role in the management of diabetic foot problems. The present work would provide experimental data of shoe upper materials that would help in choosing the right materials for making of diabetes footwear (see chapter 5)

In their research paper titled “Therapeutic Footwear in Diabetes: the good, the bad, and the ugly?” Boulton and Jude (2004) pointed out that ‘good footwear prevents foot ulceration and ‘bad’ footwear is a major cause of ulceration in diabetes. They explained that bad or inappropriate footwear causes ulceration. Similarly, Jonasson and other researchers (1990) identified footwear as the precipitating cause in the majority of toe ulcers and a significant minority of lesions elsewhere on the foot. The current work focuses on how footwear could be used to prevent or reduce diabetic foot problem through appropriate footwear design.

The Journal of American Diabetes Association published a study on “Therapeutic Footwear for the Neuropathic Foot” in 2001 conducted by Dahmen and other researchers. The publication stresses the importance of ‘good footwear’ in the management of neuropathic foot. They made it clear that neuropathy commonly occurs in diabetes and usually results in limited mobility. The outcome of their research has shown that neuropathic foot requires a shoe with maximal pressure distribution by means of a full-contact insole, a toughened outsole with an early pivot point, and shock absorption through the heel. They also pointed out that all the different parts of the footwear have their own requirements, which are closely interrelated. If this interrelationship is ignored, the shoe will have a detrimental effect on the foot. Technically, there are a number of possibilities for fulfilling these requirements, including adaptation of off-the-shelf shoes or the use of rehabilitation shoe can be a good interim solution, whereas a medical shoe seldom is. The researchers limited their study to biomechanical needs and solutions of the neuropathy foot. They could not study or discuss the materials for insoles and uppers, the techniques in preparing the lasts, or the possible shoe styles. Interestedly, the present study investigates the possible footwear materials and styles for diabetic foot.

Recently, Nathan and Singh (2008) carried out a research on “diabetic footwear: current status and future directions”. Their research has shown that prescription of diabetic footwear leads to a reduction in new foot ulceration and as a result, a reduction in lower extremity amputation rates. They explained that ill-fitting shoes remain a significant problem, especially in the elderly that diabetic patients have difficulty in getting access to shops or centers where their feet can be measured and fitted to the correct size. According to their research outcome, up to 37% of diabetic patients wear ill-fitting shoes that result in foot ulcerations. Even in non-diabetic patients, 24% wear shoes that are the wrong size, they pointed out. They added that shoe related injuries are the major cause of diabetic foot-related problems. Therefore, ill-fitted footwear is associated with most of these problems. Their study also explains that footwear needs can vary in different cultures. They state that there is a mark difference in footwear habits in developed countries compared to that of underdeveloped countries. According to their findings, in underdeveloped countries, people tend to wear sandals and slippers and some do not wear shoes at all due to poverty or religious reasons. Similarly, in this present study, structured questionnaires were designed (see appendix IV & V) to gather information from diabetic patients and medical doctors that would show the nature of footwear used by diabetic patients particularly in the developing countries (like Nigeria) and how they affect their foot conditions.

Various authors (Tagang 2010; Apelgvist et al. 1990) have given considerable anecdotal evidence and opinion to indicate that shoes can cause foot injury. They have shown that 21-82% of foot ulcers are related to pressure from footwear that is too narrow or otherwise inadequate. Mara (2011) also pointed out that if there is a delay (or inability to order) diabetic shoes for patients with at risk feet by their medical practitioners, complications such as a foot wound may develop. To further stress the point, Edmonds and Foster (2005) emphasize if shoes are not the correct size or style (see section 2.10), they can permanently damage the feet, and lead to deformity callus and ulceration.

Regular inspection of the diabetic foot by a trained professional and timely podiatry may avert the development of serious complications, such as lesion, ulcer, amputation, etc. and patients must receive appropriate instruction regarding foot care (Krentz & Bailey, 2001). But to help patients make informed choices of self-care, particularly in relation to footwear, Vernon and his colleagues (2007) believed that provision of relevant knowledge, education, and information will go a long way in improving their foot health. They further stressed that patients should be given information and assistance on how to recognize footwear broadly suitable to the maintenance or improvement of foot health and the type of footwear that should be avoided as being potentially detrimental. Prescription of protective footwear has been shown to have the potential to reduce the incidence of footwear-related ulcers and amputations (Gregory et al. 1999).

Without a proper concept of systematic diabetes foot care, patients would likely receive treatment as general foot problems, but people with diabetes who have foot problems actually need to be offered swift intervention to avoid amputation. A Study performed by Caselli (2011) to determine the causes of lower extremity amputations have identified nearly half of the amputees in their various study groups, that the initial event that lead to the amputation was either shoe-related or might have been averted by wearing appropriate shoes. The study also indicates that most of the shoe-related amputations occurred in older people with multiple foot problems, such as foot deformities accompanied by diabetes and poor lower extremity circulation. Therefore, Nather (2008) advocates that preventive strategies should be recognized and implemented to prevent or reduce foot problems.

Data from literature (Dahmen et al. 2001) has shown that neuropathy may cause changes in the form and function of the foot (see section 2.5), which may lead to ulceration and progressive deformity. They explain that these foot problems manifestations often require specially adapted footwear for the protection of their delicate feet. Therefore diabetic footwear plays an important role in the prevention of foot problems. Nather and Gurpal (2008) state that diabetic footwear has been used in the primary prevention of diabetic foot problems as well as in the secondary prevention of re-ulceration in patients who have already developed ulcers. They emphasized that repeated emphasis on foot care (proper trimming of toe nails, not walking bare foot, and avoidance of trauma) and correct selection of shoes are two basic strategies that could be adopted by people living with diabetes.

Edmonds (2005) explains that wearing unsuitable shoes which do not accommodate deforming cause by ulcers and other complications poses great risk for diabetes patients.

Looking at the magnitude of diabetic foot problems, some researchers, Jeffcoate and Macfarlane (1995); Scharfetein (2009), recommended that people living with diabetes should not wear shoes that have certain features. These features include; backless, open toe or slip on shoes, soft shoes that would not allow inversion and eversion and that would flex at points other than the location of the metatarsal heads. Therefore, to help protect and give comfort to diabetes foot, Hall (2006) and Cavanagh (2008) advocate that special or custom-made shoe that takes into consideration the various deformities in diabetes foot and that can accommodate the foot very well must be prescribed for diabetic patients.

The believed within podiatry is that footwear can have a significant influence on the foot, and that such influence can be good or bad, depending on whether the footwear is appropriate for the wearer or not. Where foot ulceration has previously occurred, amputation of part or the whole limb can occur in 50% of patients within two to five years. At an approximate cost of 20,000 GBP per amputation, a reduction of avoidable foot ulceration through footwear improvement would mean significant gains in terms of improved health economics and reduction in human misery (Vernon, 2007).

2.4.0 The Human Foot.

2.4.1 The Anatomy of the Foot.

Shoemakers' from ancient times until the end of the 18th century, concentrated exclusively on the external shape of the foot for which they were to provide a protective covering, ignoring completely what lay beneath. But in the 19th century, shoemakers realize that a shoemaker simply cannot do without knowledge of anatomy (a study of the characteristics of the bone structure, the joints, the tendons and the skin of the foot). This knowledge is important because taking of measurement of the feet for shoe construction is based on anatomical fixed points. These points can easily be recognized and they manifest only small variations when measurements are taken repeatedly (Vass 2006).

Ling and his colleagues (2008) has revealed that the foot is a complex structure with 26 bones, 33 joints and more than 100 muscles, ligaments and tendons. It is also consists of an intricate network of blood vessels and nerves. Of the 208-214 bones in the skeleton, the ones to be found in the most mobile parts of the body, the hands and the feet are among the smallest. These researchers further explained that on the surface, the foot is closely similar to the hand, but on detailed study, the foot is markedly different anatomically, biomechanically and functionally from the hand. The surface anatomy of the foot consists of medial side and sole of the foot, lateral side and dorsum of the foot (look at fig. 2.4). Vass (2006) explains that the bones, muscles, joints, and tendons of the foot jointly constitute the most complex mechanical structure in the human body. The bones form the foot's load-bearing structure whereas the muscles, which are attached to the bones with tendons, carry out the function of movements. The area of the soles of the feet totals approximately 46 square inches (300sq.cm) which must reliably bear an average body weight (for men) of between 70-120kg on standing.

The foot is therefore seen as a complex anatomical and biomechanical structure. Therefore, a thorough understanding of the structure of the foot is essential for designing diabetic footwear in order to avoid the consequences of nerve injury, poor wound healing and disrupted function (Edward & James 2011). Anatomically the foot consists of three sections namely; tarsus, metatarsus, and phalanges (Chen 1993; Ahonen 2008; & Donatteli 1990).

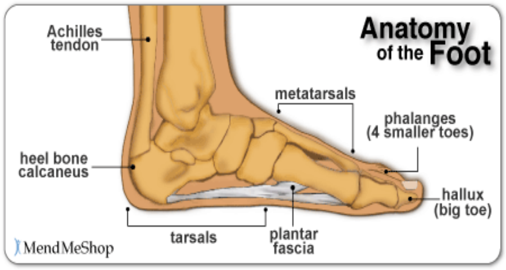


Image I

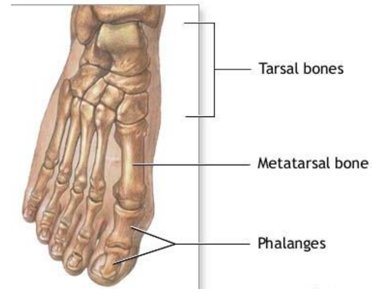


Image II

Image III

Image IV

Fig.2.5 Different views of the anatomy of the foot.

Image I available at: http://health-advisors.org/plantar-foot-anatomy/;

Image II Available at: www.health.rush.edu/healthinformation/hiemultimedia/ and

Images III & IV are available at: http://www.myfootshop.com/images/anatomy/lateral_foot_mod_labeled.

The Tarsus: The tarsus is where the bulkier and larger bones are clustered. There are seven bones in the tarsus, the biggest bone at the rear of the foot is referred to as the calcaneus or heel bone. On top of the heel bone is the talus bone which connects to the leg. In the anterior part of the talus is the navicular, a boat-shaped bone, and little lower down, toward the lateral side is the cuboid, which joins the calcaneus. In the front of the navicular, there are three cuneiforms.

The metatarsus: These are the longest bones in the foot that articulate with the tarsus and comprise the proximal part of the fore foot. There are wide spaces between the metatarsal bones to give them room to spread a little when weight is borne on the foot. The 1st metatarsal bone is located on the medial and the 5th on the lateral side of the foot. It can be noted from fig. 2.5(II) that the second metatarsus is the longest one. The metatarsal heads (the rounded forepart of the metatarsal bones) are in contact with the ground. These comprise the ball joint of the foot and form what is known as the anterior (transverse metatarsal) arch. This part of the foot serves in a limited way as a shock-absorbing structure.

The Phalanges: The phalanges or toes have fourteen toe bones. The big toe, also known as hallux (see fig.2.5-I) has two phalanges whereas the other four lesser toes have three phalanges each. A study carried out by Erikson (2009) on the management of neuro-ischaemic foot ulcer has shown that structural changes to the foot can cause new ulcer to develop.

2.4.2 Biomechanics of the Foot.

The foot is described as a feat of engineering that has 26 bones which work flawlessly in unison with all the muscles with such precision that we often take for granted the amount of co-ordination that goes into such tasks as running, jumping or walking (Tan 2008; Nigg 1986). The foot goes through what is called 'Gait Cycle' (see fig. 2.6 & 2.7) during normal walking and gait comprises of two phases, namely; the stance and the swing phase. The period which the foot is in contact with the ground during walking or running is referred to as stance phase (see fig. 8 below). Whereas the swing phase is explained as the time during which the foot is lifted in the air and is not in contact with the ground (Tan 2008).

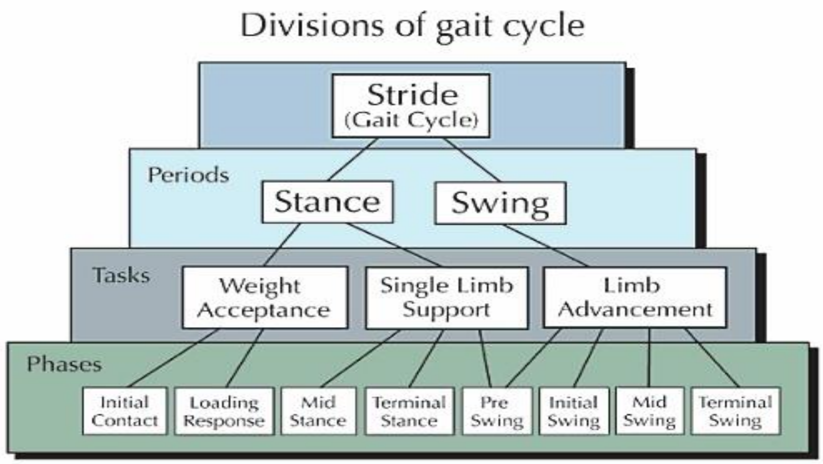


Fig. 2.6. Divisions of Gait Cycle. Available At: www.pediatricpt.co.kr/ (Accessed on 22/07/2013).

Fig. 2.7. The Stance Phase of the Gait Cycle. Maffetone (2012).

It is common to find irregularities in gait with people suffering with diabetes. A study conducted by Petrofysky and other researchers (2006) has revealed that gait is impaired in people with diabetes and that there is more unsteadiness and tremor at the knee, hip and ankle in patients with diabetes during gait compared to the general population. But Cohen (2011) has pointed out that correct management of diabetic foot problems can improve gait and allow diabetes patients to fit into their work and leisure shoes.

During each phase of the gait cycle, the foot experiences varying magnitude of pressure. For example, during the heel strike phase, the heel of the foot experiences high amount of pressure, while the fore foot bears most pressure during the heel off phase. This explain why ulcers of the foot often occur at the heels and ball of the feet rather than at the mid-foot (Donatelli 1990; Tan 2008; Owings et al. 2009; Waaijman et al. 2012). Therefore, a stable stance, ambulation and effective transfer of force through the lower limb is important to avoid the consequences of nerve injury, poor wound healing and disrupted functions. This is considered as an essential part of orthopaedic practice (Rensburg 2011; Edward & James 2011).

> "In addition to emphasis on optional blood glucose control, it is important that altered biomechanics in the diabetic foot must not be neglected" Tan 2008 p.74.

It should be therefore noted that footwear acts as the interface between the body and the ground during gait, in addition to protecting the feet from potentially harmful environmental factors. Footwear can be modified to alter mechanical loads on the lower extremity generally during the stance phase of gait (Working feet and footwear n.d) and whenever special footwear is provided, the supplier should make sure that it fits properly and allow the toes a wiggle room (around 10mm or 1cm gap between the longest toe and the end of the shoes).

Gait adaptation to footwear modifications can be divided into three phases according to Mundermann (2004) namely: Short-term, medium-term, and long-term adaptation. Short-term adaptation may be considered as immediate adjustment of the body's gait mechanics to a modification in footwear. The medium-term adaptation is described as adaptation to footwear modifications that occurs within a few days of using a new footwear modification. During long-term adaptation phase, the body "fine tunes" its gait mechanics, possibly to minimize energy and improve gait efficiency.

A research work on the effects of common footwear on joint loading in osteoarthritis of the knee by Shakoor and his colleagues (2010) has shown that the entire lower extremity is considered to be an interrelated functional and mechanical unit, and alterations at one aspect of the lower extremity (e.g the foot) can have serious impact on distant areas such as the knee. Therefore, they concluded that footwear design and several aspects of footwear may substantially affect the loading patterns of the entire lower body. They pointed out that the heel lifts and heel height in walking shoes may affect loading. The ‘stiffness’ imposed by shoe soles is another characteristics of footwear likely to affect joint loading. And Mueller and his co-researchers (2006) reported that therapeutic footwear and orthotic devices are capable of protecting the foot from excessive plantar pressures during walking.

Previous studies (D’Ambrogi et al. 2005) have pointed out that peripheral neuropathy is responsible for remarkable changes of both structure and function of the foot in diabetic patients. They also observed alterations in plantar pressure distribution in diabetic patients with and without neuropathy, thus suggesting that functional changes may occur before neuropathy becomes evident.

Human walking analysis (Versluys 2009) has shown that during walking, there are periods when only one foot is on the ground (single support) and a period when both feet are on the ground (double support). Versluys (2009) analysed that double limb support occurs for two periods of 12% of the gait cycle and single limb support occurs for two periods of 38% of the gait cycle (in intact walking).

From biomechanics point of view, the main goal of footwear is to redistribute force over a large area (that is, to reduce pressure), thereby cushioning foci of elevated pressure. Normally, an insole that conformed to all curvatures of the foot can be used to redistribute the pressure throughout the surface of the foot. But it is important to identify how much the patients use their feet and in what activities. This knowledge about both the amount and type of use of the feet is critical because, for example, much greater forces are transmitted through the planter tissues from running than walking. And a patient who is chair or bed bound might not need sophisticated footwear to protect the feet, whereas a very athletic patient who has significant foot problems might have to consider changing or altering his or her behavior as well as footwear (Bowker & Pfeifer 2008)

The result of a research work carried out by De Castro and his colleagues (2010) show that wearing inappropriate shoes can cause biomechanical inbalance, foot problems, pain and induce falls. The outcome of their work indicate that the percentage of the participant wearing shoe sizes bigger than their foot length was 69.2% for the men and 48.5% for the women.

The method to design diabetic footwear is based on characterization of the biomechanical variables appropriate to footwear design. "Of most importance for a diabetic foot is the high pressures under the 1st MTP (metatarsophalangeal) joint. High pressures under the 1st MTP joint are known to be associated with ulceration" (Bernabeu et al. 2013, p. 977).

2.5. 0 Footwear Materials

Footwear materials are described as "natural and synthetic materials which are suitable for footwear manufacture or repair and have adequate wear properties as upper or sole materials" (British Standard, 2007 p. 4). There can be few solid materials in the world which at some time or the other have not been used for footwear (Thornton 1970). Materials like, leather, fabric, wood, brass, glass, iron, e.t.c, are among the numerous materials that have been used or are used for footwear manufacture. But the choice of any of the materials mentioned above for shoe making would be a factor of its availability and suitability.

2.5.1 Upper Materials.

Footwear upper materials are manufacture from a wide range of materials. The material which must have the necessary properties for making shoe uppers may be leather, woven, non-woven or knitted fabrics in natural and synthetic fibers, or polymers (Larcombe 1975). Leather stands out as the most suitable material for footwear manufacture, but synthetic alternatives have been invented. The synthetic alternatives are mostly used in making ladies' fashion footwear, mainly because the cost to produce them is lower than that of natural leather products (Covington 2009).

> "The elegance and durability of a shoe depend to a crucial extent on the quality of the materials used. In consequence, the first rule of shoe making is to exercise great care when selecting the leather for the upper and sole of the shoe" (Vass, 2006 p.96).

Therefore, leather is seen as the most effective material for shoe upper because of its properties of plasticity and elasticity (Tyrrell & Carter 2009).

Leather: Leather is animal hide and skin so treated chemically as to make it permanently more resistant to decomposition, particularly when wet (International leather training class, 2001, Covington 2009). It is also described (Willcox 1975) as the pelt of an animal which has been transformed by tanning into a stable, non-putrescible, flexible sheet material. But it can be made as stiff and as tough as wood, as soft and flexible as cloth and anything in between (Covington 2009). Leather is considered as the most suitable material for the manufacture of footwear based on the fact that it provides the foot with good protection against injury, adverse weather conditions and it is extremely easy to work (Vass 2006).

The suitability of leather for shoe manufacture is based on certain properties, namely; its abilities to exclude water, but allow air and water vapour to pass through the cross section of the upper. This is also referred to as water absorption and water-vapor permeability. Leather has good elastoplastic and viscous properties which provide reliable shape stability after stretching-lasting operations in shaping footwear on last (Ol'Shanskii et al. 2009). Covington (2009) explains that these properties are the basis of 'foot comfort' and are so important that many attempts have been made to mimic them in synthetic materials, the so called poromerics. To date, none has been successful. Leather remain the preferred material of choice for shoe making because of the way it feels, the way it interacts with and moulds to the feet, the way it looks and the way it wears in use.

Leather has excellent performance properties such as high hydrothermal stability of modern chromium (III) tanned leather which allows it to be used in rapid mass production processes, in which shoe uppers are moulded directly onto melted polymeric soles. It also has good plasticity and elasticity properties, which allows it to be moulded to shape and will retain that shape unless it is subjected to moisture and heat. It is especially suitable for footwear manufacture due to the fact that a wide range of finishes, colors and textures can be applied to it (Tyrrell 2009; Covington 2009; O'Flaherty 1978). Commenting on the suitability of leather for shoe making, Willcox (1975) states that there is no other material that affords such universal comfort regardless of the season.

Generally, properties of leather depend on the origin of the raw materials (that is, hide or skin), how the hide or skin is prepared for chemical modification, how the modification is conferred chemically, how the leather is fatliquor or lubricated and how the surfaces are prepared (Covington 2009).

The above mentioned comfort properties make leather desirable for those portions of the footwear which are in intimate contact with the foot. Normally, if leather is used as shoe upper, the absorption of foot perspiration does not constitute a problem. The part of the shoe which is exposed to perspiration, usually consists of two types of leather viz; the shoe upper leather (mainly chrome tanned) and the insole, usually the product of a vegetable tannage (O'Flaherty 1978). The upper leather is prepared and strengthened during the various tanning processes and different reinforcements are also added as the shoe is made. Bespoke shoes are always lined in order to cover the reinforcements and stiffeners, so as to make the shoes much more comfortable to wear. The lining covers the reinforcements, which would otherwise rub the wearer's feet. During the manufacturing of the shoes, it is important that the seams of both the upper and the lining are not placed in direct proximity to each other because then they would tend to press and chafe the foot. In order to reduce the number of seams inside the shoe, the lining should be made of as few parts as possible. To achieve this, the patterns that the clicker uses to cut out the parts of the lining should be drawn separately (Vass 2006).

According to Vass (2006), lining made of vegetable tanned leather ensures that the skin of the wearer's feet can breathe naturally. Because the air and moisture permeability of calfskin is outstanding, and it is elastic, pleasantly soft, and extraordinarily hard wearing, it is considered as the best material for lining bespoke footwear.

Feet perspire and if footwear does not breathe very well, foot problems will ensue. Perspiration varies with individuals, but both composition and flow of sweat depend on external and internal conditions. For the whole foot, under moderate strain, a figure of 6-7mg per square centimeter per hour has been arrived at. The feet represent about 7% of the body surface or approximately 1,200sqcm and it has been stated that the entire body gives off 1% of its weight in sweat per day (O'Flaherty 1978; World Footwear, May/ June, 2006).

2.5.2 Insoles and Inserts

The reduction of high plantar pressure in diabetic foot with peripheral neuropathy using appropriate insole is mandatory for prevention of ulcers and amputations. An orthotic is used to provide an interface between the foot and the shoe. Therefore, it is expected that the upper surface of the orthotic must match the anatomical profile of the foot, with adaptations as required, and the undersurface must always match the innersole of the shoe. When prescribing orthotic to diabetes patient, it is important to consider if the footwear has sufficient length, width, and depth to accommodate the orthotic. There should be enough room within the shoe to fit the foot and the orthotic. If the footwear is inadequate, the therapeutic will fail (Tyrrell 2009; Pataky et al. 2010).

Bonnie and his colleague (2004) revelation on the 'effectiveness of insoles on plantar pressure redistribution' show that the use of insoles could reduce local peak pressure and increase the contact area significantly. They show that contoured insoles are significantly better than flat insoles in respect to the insole functions in reducing local peak pressures. A recent study (Kari 2010) indicates that increased plantar foot pressure is a leading cause of ulceration in the diabetic population. To help prevent ulcer formation in high-risk diabetic patients, Reiber (1994) recommended wearing appropriately fitted custom-made shoes with accommodative inserts.

Many foams and viscoelastic materials are used in shoes as insoles. Porous polyurethane sheets of 3-10mm thickness can be used based on the patient's specific need. The required mechanical and cushioning properties of insole or orthotic material for individual patient can be achieved by developing material with required thickness and density by changing the polymer content, polymer concentration and solvent volume (Saraswathy et al. 2009).

Foot orthosis is a device that is placed inside footwear that acts as an interface between the footwear and the weight bearing surface off the foot with the goal of correcting foot problem through providing support for the foot during weight bearing (Muogboh 2000).

Pressure from wearing normal shoes and minor traumas are more likely to lead to ulcers. Hence, in 1993, the U. S Congress passed The Therapeutic Shoe Bill (TSB), that defined the benefits of wearing preventative footwear and so cleared the way for government and private insurance to contribute 80% of the cost of such footwear up to a maximum of $330 (World Footwear 2003). The study also outlined the different orthotics used in diabetic footwear. It shows that foot orthotics fall into two general categories-functional and accommodative. Orthoses for diabetic footwear fall into the latter category (also called sock-liners, inserts or inlays), which are fitted into the foot-bed of the shoe. They treat common foot ailments such as heel pain, metatarsal pain, tendonitis, painful lesions, arthritis, as well as the diabetic 'at risk' foot. The article further explains that the orthotics used in diabetic footwear may be custom- moulded or pre-moulded, as long as they are made from a suitable dual or multi-density material and are moulded to be in total contact with the plantar surface of the foot. In contrast to the above mentioned study which emphasis was on orthotics for diabetic foot, the present study would only investigate diabetic footwear material choices and design.

2.5.3 Soling Materials

Table 2.1 shows that there is an ever-widening choice of sole materials. The choice could be wider than it appears from the table because majority of these materials can be compounded together in varying proportions.

Table 2.1 Range of soling materials available in each decade (Source: Steve Lee Associates; In: Price 1999. p.4).

1930	1940	1950	1960	1970	1980	1990	2000
L **NR**	L NR VR	L NR VR	L NR VR PVC	L NR VR PVC PU TR TPU	L NR VR PVC PU TR TPU EVA	L NR VR PVC PU TR TPU EVA LR	L NR VR PVC PU TR TPU EVA LR POE
L Leather **NR Natural Crepe Rubber** **VR Vulcanised Rubber** **PVC Polyvinyl Chloride** **PU Polyurethane (Reaction Moulded)**				**TR** Thermoplastic Rubber **TPU** Thermoplastic Polyurethane **EVA** Ethylene Vinyl Acetate **LR** Vulcanised Latex Rubber **POE** Polyoefin Elastomer			

In early days, rubber was used as a cushioning material. And research (Rodrigues 1997) has shown that vegetable tanned leather soles are healthy because they discharge heat and provide a less stressful environment for the foot. But in recent years, shoe manufacturers have resorted to using polyurethane (PU) and Ethylene vinyl acetate (EVA). These materials have the ability to deform and conform to body shape so that pressure concentration in 'diabetic foot' is avoided (Goonetilleke 2003). In addition, PU can be blended to be solid, cellular, flexible or rigid. Its other features include light weight, and the most durable of the cellular solings at equivalent density (SATRA 1983).

Polyurethane (PU) has established itself as a major alternative to traditional soling materials such as leather and rubber. Its big advantage over other materials in the design of diabetic footwear is it combines excellent physical properties with light weight to produce footwear that is both extremely durable and comfortable to wear. Its principal footwear application is as microcellular compounds used to produce single or dual density soling, either as unit soles or by direct moulding onto the last.

2.6.0 Design

Information obtained from patient UK newspaper (www.patient.co.uk) gives certain features to critical consider when designing shoe for diabetic patients. It pointed out that the shoe should be deep and wide to allow room for custom pedorthic insole with a roomy 'toe box' to prevent squeezing of the toes. The specific considerations for each part of the shoe as gathered from different sources are given below:

2.6.1 The Out-Sole.

A number of investigators, Cavanagh and Ulbrecht (2008), have shown that most common out sole suitable for diabetes is the rigid rocker-bottom shoe or a variant thereof called a roller. The rocker has a break in the contour of the out-sole, whereas the roller has a smooth curve (see fig.2. 8). The general principle behind both designs is that they allow the patient to walk with minimum motion of the joints of the foot.

Fig.2.8 Example of rigid out-sole. Available from:
http://www.hiclarks.com/images/clarks-mens-shoes/clarks-mens-shoes-13.jpg

2.6.2 The Insole

The insole is the component immediately underneath the foot in a shoe. It is important that the material used for the insole is strong enough for the upper to be secured with tacks, adhesive or stitches which are used in lasting. Janisse and Coleman (2000) point out from their study on "Pedorthic Care" that there are a great variety of insole materials available for shoe designers to use. They stated that softer polyethylene materials help to cushion the foot but cannot fully replace capabilities of human soft tissues. These materials are easily moulded and trimmed. According to Owing et al. (2008) custom insoles are frequently prescribed for individuals with diabetic neuropathy to offload high pressures from the metatarsal heads (MTHs) and other areas, which reduces the risk of plantar ulceration. They also explain that insoles provide the important interface between the foot and the shoe and, together with outsole modifications, offer the most direct approach to the reduction of potentially damaging tissue stresses on the plantar aspect of the foot.

According to Cavanagh and Ulbrecht (2008), the preference in insole design for long term wear is a lamination of different materials or a single firm material.

2.6.3 The Upper

During design and construction of shoe, attention must be given to the specific parts of the upper as this part greatly affects shoe fit. The areas of the foot to be critically considered when designing footwear for patients with diabetes are (Bernabeu 2013, Hartless 2008): Counter (the part of the footwear extending around the heel-look at fig.2.9); Vamp (the part that covers the instep); Toe box (part of the shoe that covers the toe area) and the throat (the part at the bottom of the laces).

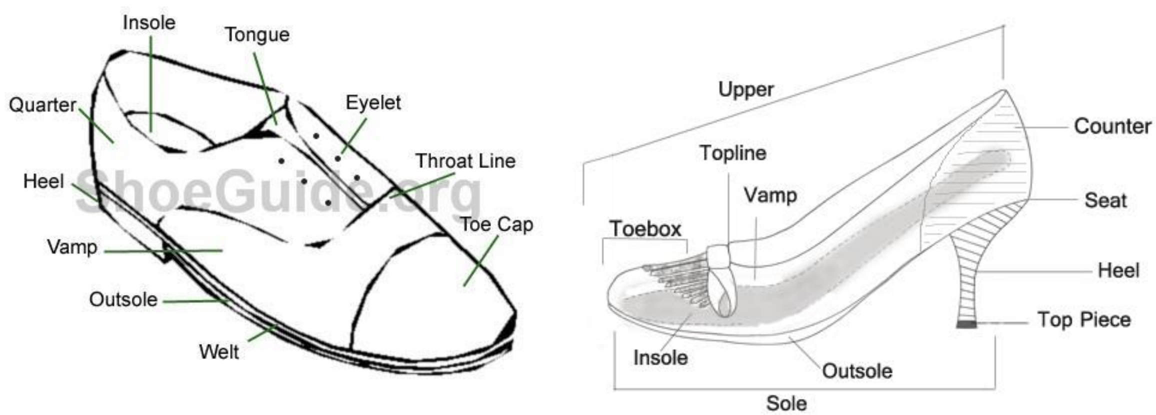


Fig.2.9 Shoe Anatomy: Available at: http://www.google.com.ng/webhp?source=search (Accessed on 01/08/2013).

2.7 Construction Methods

The shoemaker in the course of his work will fit one part or component of the footwear into another, adjusting them over or below each other, thus building a flat surface of the leather of the upper into a three-dimensional shape (Laszlo 2006). The way in which footwear is made is known in the trade generally as the ‘method of construction’. The literature (Tyrrell and Carter 2009; Miller 1976;) provides the following methods of constructions.

1. Direct stuck or cemented construction: The method consisted originally of tack-lasting the upper under the insole (“in-lasting”) and attaching the sole with adhesive to the bottom of the shoe. This method of construction is the most widely use construction, both in the volume footwear industry and in the orthopaedic footwear manufacturing.

Tyrrell and Carter (2009) outlined the stages involved in the process for cemented construction as follows:

- Upper, lining and inner sole prepared
- Cement applied to the lasted edge of the upper and inner sole
- Stiffener inserted between the upper and lining, and in the heel area (heel counter).
- Last inserted and inner sole accurately positioned to feather edge
- Shank and filler inserted
- Undersurface scoured.
- Sole attached with cement
- Heel attached.
- Shoe removed from last.
- Inner sole lining inserted.

It is important that temporary tacks or staples used to hold the insole during the lasting process are removed before sole attaching because any temporary tacks accidentally left in could cause injury to the wearer's foot. Thus, shoemakers and machinery manufacturers would have to work towards eliminating the use of tacks or staples by replacing them with cement lasting completely.

2. Moulded Construction: The direct vulcanization of rubber soles on to the bottom of tack lasted shoes and boots was one of the earliest methods of moulded construction. But this method was superseded by the injection moulding of PVC. Injection moulded PVC involves the direct injection of molten PVC on to the bottom of the shoe. P. U. Injection moulding is most recent method of direct moulding developed in the late 1960's. It is extremely self-adhesive and it is also known to have better wearing qualities than any other soling material of comparable density.

3. Veldtschoen or Stitched down construction: In this method the upper material is flanged out wards during the lasting operation and attached by adhesive and stitching to a layer of material known as the runner or middle.

4. Machine welted construction: Special insole having a rib or wall is commonly used. During the construction, the upper is in-lasted to the rib by means of wires and staples or more recently by adhesion. Usually a strip of leather, the welt is sewn to the upper and ribby means of a chain stitch. The welt, having been beaten flat, then has the sole attached to it by adhesion and lock-stitching. This method of construction is used for the manufacture of high quality expensive shoes. It is expensive because of the high labour content in producing footwear using this method. Also, the use of all leather uppers, soles, and heels adds to the total cost.

5. Force Lasted or Californian slip lasted: In this method, a sock, a strip of material (known as the plat form cover) and the upper are stitched together around the feather edge. This is commonly known as sock and plat form stitching, the result being an upper which is partially shaped before lasting. Usually, when the upper reaches the making room during manufacturing, the last is ‘slip’ or ‘forced’ into the upper. This method of footwear construction is being utilized for footwear manufacture where comfort is the main criterion.

6. String Lasting: Often this method is used in conjunction with injection moulding. Afetr the normal closing operations have been completed, a strong string is attached by means of an over lock stitch to the lasting edge of the upper to the last and drawing the string either by hand or by machine, then tying the ends.

2.8 Technical Requirements of Diabetic Footwear.

Currently, little or no practical information are available to the foot-care provider in regards to the choice of footwear materials used in diabetic footwear. According to Foto

(2008), the information provided by manufacturers on therapeutic and diabetic footwear are static data such as apparent density, compression set, etc.

As pointed out in sub section 2. 6.1, the upper material of diabetes shoe should be breathable. This means that the material should be able to pass air, water, and water vapor and, or perspiration by evaporation or absorption from the foot to the outside environment (SharpHouse 1978).

From the above point of view, leather has been found (Jone 2000), to be suitable for diabetes footwear manufacture because it is permeable both to water and water-vapor. But, rubber and synthetic plastic materials, such as polyethylene sheet, are normally quite impermeable to air, water and water-vapor. This reduces their suitability for shoe upper material which covers a large part of the foot. Dugdale and Zieve (2009) emphasized that diabetic patients must wear shoes that are made of materials that can breathe.

According to Cavanagh and Ulbreacht (2008), diabetes footwear should be made of a rigid or firm outsole. They explain that rigid shoes appear to reduce pressure because they allow the patient to ambulate without extending the toes (at the metatarso-phalangeal joints). The insole need to be very soft to help to cushion the foot and the shoe should be made of no or low heel (Janisse & Coleman, 2008; Rahman 2003); Dugdale & Zieve 2009).

2.9.0 Shoe last/ Lasting

2.9.1 General Last

Shoe last is considered as the most important component of shoemaking. It is a Solid 3D model form or shape around which a shoe is made. It is made from many measurements that are statistically determined (Tyrrell & Carter 2009). Footwear last is closely related to the foot (see fig. 2.10) and it is made based on certain factors like the foot shape and size, comfort parameters, shoe style, type of construction, etc. (Shuping et al 2010).

Shoe lasts are made of plastic materials, but in some cases, they could be made of wood. They are usually made with hinge in order to ease removal from the shoes without causing any damage to the shoes and for the purpose of reusing as many times as the factory chooses (Tyrrell & Carter 2009).

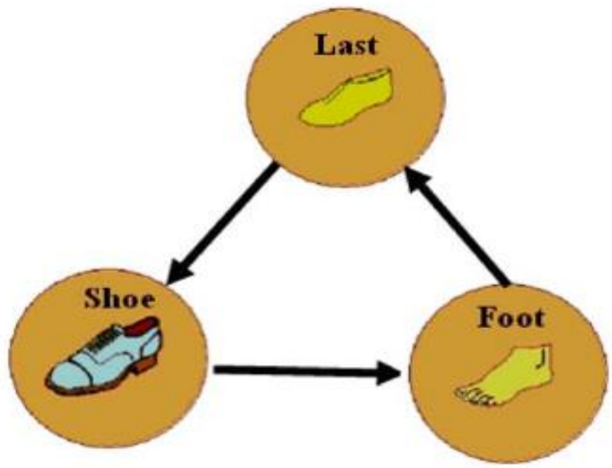


Fig.2.10 Foot-Shoe-Last Triangle (Shuping et al. 2010. p.12).

2.9.2 Bespoke Last

Shoe last customizing systems (see fig.2.11) are very important for designing footwear for people with diabetes (particularly for those with foot problems or at risk of developing ulcers). But in some cases, modification of an existing last in order to reduce the risk of foot ulceration and at the same time preserving the style of the shoe may be adopted. The shoe last may be made completely by skilled craftsmen or by using a Computer-Aided Design/ Computer-Aided Manufacturing (CAD/CAM). CAD tools (e.g shoemaster creative) can be used to support the whole last/ shoe design and manufacturing process (Tyrrell & Carter 2009; Bernabeu et al. 2013).

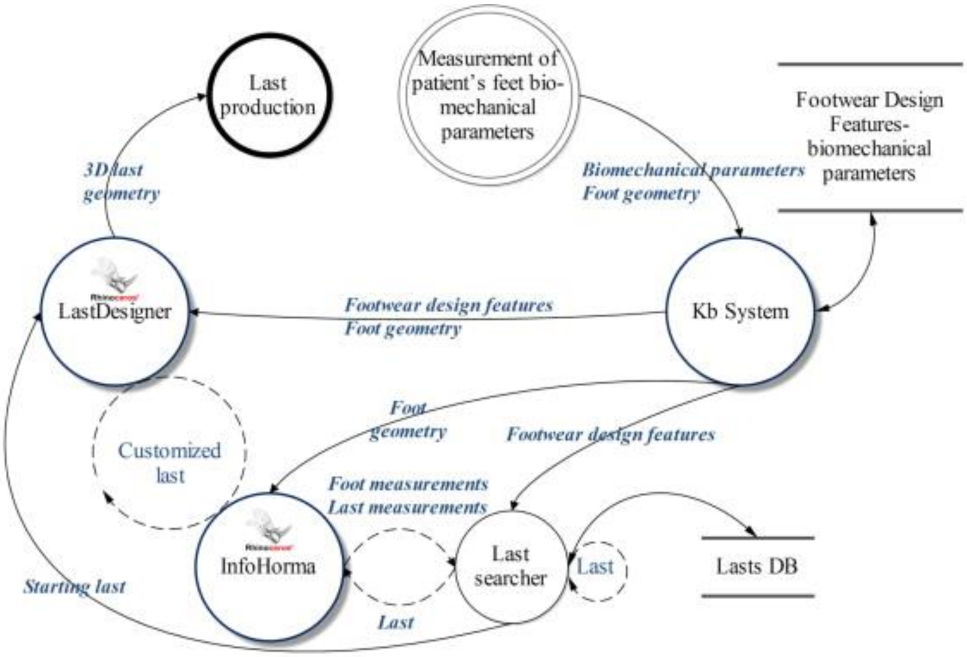


Fig. 2.11 Shoe last design process for diabetic patients (Bernabeu et al. 2013. p. 980)

2.9.3 Lasting

After closing the shoe upper, it is taken to the next stage, shoe lasting section, where it is fixed on the last. The shoe lasting unit consists of six subunits (as shown in fig. 2.12).

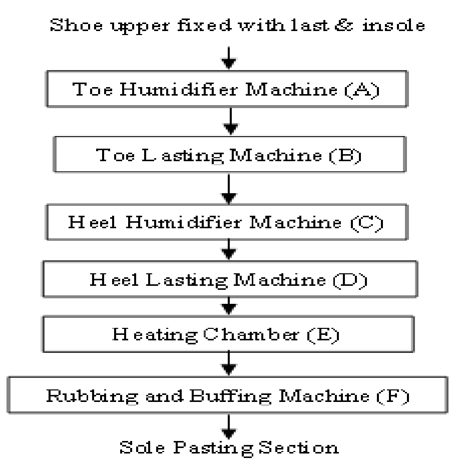


Fig. 2.12 Flow diagram of shoe lasting section (Modgil, Sharma & Singh 2012 p.45)

Lasting Methods: There are different methods of lasting for particular types of construction. The following are the most common (SATRA 1983).

Flat Lasting: This system can be used for a wide variety of constructions. The upper is pulled over the last and attached to the underside of the insole by adhesive or tacks. The shoe bottom may be stuck on, stitched on or moulded on.

Lasting to rib: In this method, the upper is shaped over the last and attached to a rib on the underside of the insole by wire staples or adhesive. This method is commonly used for Goodyear welted footwear.

Flanged Lasting: This method of lasting is used for the veldtschoen or stitchdown constructions. The upper is shaped over the last with its edge turned outwards to be stitched to the upper surface of the runner, or in the case of a single sole veldtschoen, directly to the sole.

Slip and force Lasting: In this method, the upper is not shaped over the last but is first stitched to a sock which takes the place of the insole. The shell is shaped by forcing the last into it.

String Lasting: This method is used mainly for slippers but can also be used for some shoes and fashion boots with PVC coated uppers. The upper is prepared with the pull strings in the closing room. The string, which is held to the edge of the upper by overlock stitching, is drawn tight so the upper conforms to the shape of the last.

2.10.0 Foot Measurement and Footwear Sizing.

2.10.1 Foot measurement.

To be able to make shoes to an individual correct shoe sizes and to eliminate guess work, accurate measurement of the foot is required. The result of foot measurement carried out by Olivato (2007) and Tagang (2010) show that foot morphology differs significantly based on geographic area of an individual origin. To obtain correct measurement of foot, the procedure (Miller 1976; Nishi 2008; Lambert 2009) outlined below is therefore recommended.

There are many devices that can be used to measure the foot for footwear design/ manufacture and fitting. Example of such device is the Brannock Foot-measuring Device. The device (see fig.2.13) was design in 1927. It is used for footwear fitting environments. The device has been described as being accurate, simple, and functional.

Fig.2.13 The Brannock Foot-Measuring Device. Available from: (http://www.algeos.com/html/products/brannock.htm.

Step 1: Gather the measuring tools and materials; measuring tape, piece of paper larger than the foot, a pencil, and a ruler. Tape the piece of paper at corners, to a flat, hard surface on floor.

Step 2: Trace the outline of the foot. Because some people have feet that swell especially in the evening after standing on them for long periods of time, it is recommended that measuring of the foot should be done in the evening to allow for comfort and ample room. Trace the foot without shoes, just socks that will be wore with the shoes. Then, the foot should be placed firmly on the floor, outline the foot on the paper. The pencil should be held straight up as the tracing process is carried out. Also, the pencil should be firmly placed against the foot when tracing.

Step 3. Mark the length and width of the foot. Using the pencil, draw a straight line from top to bottom of the outline of the foot. That gives the length. Then from side to side at the widest part of the outline, draw another straight line. That gives the width.

Step 4. Use the measuring tape or ruler to measure from top to bottom of the outline of the foot. Record the measurement. Do not round up or down as this will affect the fit of new shoes.

Step 5. Use the measuring tape or ruler, measure the width of the foot. Measure the foot outline from left side to the right of the widest part of the outline of the foot. Record the measurement.

Step 6. Use the measuring tape to measure the circumference of the foot at the instep, ankle and at other heights.

Miller (1976) pointed out that different styles of shoes made on different lasts using different materials vary in their ability to provide a satisfactory fit for people whose feet vary in length and joint girth. He stresses that a foot survey is required to provide the footwear and last manufacturers with sufficient information to allow them to:

- produce a pair of model size lasts on which footwear can be made which will give the desired standard of the fit to people whose feet are of the model size and fitting, and as large a range as possible of those with feet that are longer and shorter and wider and narrower.

- to select the people to try on the test footwear whose feet can be compared with the average feet of the size and fitting the model footwear or shoe is made to and whose feet can be compared with those of the segment of the market that the footwear to be made on those lasts will be designed for.

- to indicate the range of sizes and fittings required to satisfy the fit needs of that segment of the market.

- to select the people as in (2) above to try on the test footwear produced in the fittings and a selection of the sizes that will be manufactured after consideration of (3) above and the cost of meeting those needs.

The points mentioned above all point to the fact that accurate measurement of the foot is required to be able to make shoes to an individual (diabetes patients) shoe size and to eliminate guess work. For proper fitting, it is therefore recommended (Olivato 2007) that diabetes patients must ensure that their feet are measured correctly before they buy new shoes.

Another study titled “Shoes from serial production in different width sizes- an urgent need or caprice?” carried out by Urbancic-Rovan and other researchers (2010) pointed out that ill-fitted footwear can cause diabetic foot ulceration. They found out from their study that there is a significant difference between the size of the right and left foot in at least 25% of the general population. In 154 patients, they analyzed foot length (L), width (W) and perimeter (P) (at the level of MTP joints). They concluded that a slight difference in length (less than 1 length-size unit) between the left and right foot, and wide variation of foot width indicate that the majority of their patients would not need shoes of different length size, however different width sizes should be available. Similarly, the present work will study the differences that may exist between the sizes of an individual feet and the required tolerable allowance (see chapter 7).

2.10.2 Shoe sizing

Many people assume they know their correct shoe size, but result of a research conducted by doctors at New York University Hospitals and published by the Harvard Health Letter (2011) showed that 35% of people are off by at least half a size. The publication also revealed that more people in the West are buying shoes on-line, so going to a shoe store to get their feet measured is becoming a thing of the past. Whereas the right pair of shoes can ensure a comfortable means of maintaining a mobile, healthy lifestyle, the wrong pair of shoes can literally knock a diabetic off his or her feet (World Footwear 2008).

The footwear sizing system is majorly based on foot length and sometimes is based on foot length and foot width. Some footwear manufacturers however, are using length, width and girth measures, and a mismatch in any dimension can results in poor fitting (Goonetilleke 2003). Appendix VI provides the different footwear size systems for adults and children that have been developed worldwide.

Three essential measurements are required to determine shoe size namely; the overall foot length (that is, heel to toe), arch or ball length (that is, heel to 1st metatarsophalangeal joint), and width. The proper shoe size is considered as the one that accommodates the head of the 1st metatarsal (that is, the widest part of the foot) in the widest part of the shoe. That is why shoes must be fit by arch length rather than by overall foot length (Caselli 2011).

2.11.0 Footwear Fitting and Fastening.

2.11.1 Footwear Fitting.

Proper fitting of shoe according to Goonetilleke (2003) involves understanding feet, shoes, and the selection of shoes to achieve a required fit. Vernon and his colleagues (2007. P.) categorically state that "*while ill-fitting footwear may cause superficial yet painful problems, such as corns and callus in the healthy population, more serious problems, including foot ulceration can arise in the at-risk population"*.

Therefore Litzelman (1997) reported that a properly fitted shoe which has been manufactured from soft materials with a sole designed to absorb shock, is sufficient to protect sensate feet, even in diabetes patients.

Shoe fitting is best accomplished according to White (2010) by having the patient try on shoes from a fitting inventory. Such an approach allows the fitter to best determine the footwear size to order, and to allow the patient to see and feel how the shoes will fit at the time of dispensing. It is recommended that patients who cannot be satisfactorily fit in depth shoes must be fit with custom-molded shoes.

In order to avoid the tendency of therapeutic shoes harming patients, they must be fitted by experience person or supplier. It is recommended that shoes should be fitted only by practitioners trained in fitting shoes to the diabetic foot and to ensure good fit, suppliers should have a large stock of depth-inlay shoes in different styles and brands (Wooldridge et al. 1998). Normally, when trying on the shoe, the wearer must be certain there is enough room for the toes at the sides and front, as well at the top, so that these parts of the shoe do not put pressure on his toes. To make sure you have enough room in front of your toes, Gilmore (1981) recommended that the thumb should be pressed across the tip of the shoe; the fit is correct if the thumb does not overlap the longest toe. In other words, the shape of the footwear must match the shape of the foot (see fig. 2.14). Chen (1993) pointed out that most complaints that relate to pains in the forefoot such as hallux valgus and on top of toes might be caused by continually wearing a pair of shoes with insufficient width and lack of enough accommodation at the forepart region.

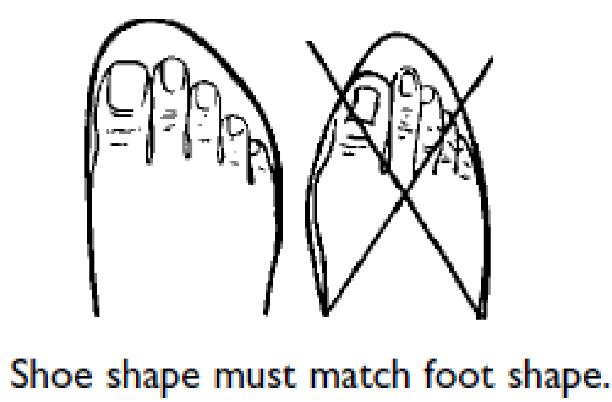


Fig. 2.14 Foot shape and shoe shape (National Diabetes Education Programme, 2000. p.14).

Pezza (2011) in explaining the importance of footwear in podiatry practice, outlined 4Cs of shoe fitting which are “Care, Convenience, Compliance, and Cash”. She pointed out that podiatrist would be able to help their patients to reap the benefits of therapeutic shoes program if they follow all the rules, and ensure that patients have everything they need to maintain good foot health.

It is generally believed that product performance can be broadly evaluated based on its function, form and fit. Product compatibility or fit is necessary for someone to experience comfort, safety and satisfaction during use. It is observed that manufacturers attempt to design and develop footwear so that they provide a covering for the foot while exhibit fashion or style. But the design and development of footwear must cater for the varied perceptions of fashion and style while taking into high consideration the product compatibility (Goonetilleke 2003). A study conducted by Silvester and other researchers (2010) on ‘choosing shoes’ has shown that although fit and comfort are perceived by patients to be important factors in choosing footwear, current footwear choices are always inappropriate. Their work has pointed out the need for good footwear and the need to improve both practitioner and patient knowledge of footwear.

According to Sandrey and his colleagues (1996), properly fitting shoes are important in the prevention of injuries. They pointed out that foot length should not be the only consideration used to determine proper shoe fitting. Static and dynamic measurements for the right or left foot, as well as metatarsal width, fifth metatarsal length, and heel width should also be included. Proper fitting of footwear (Janisse 1992) can be achieved as follows:

- Measure and fit shoes at the end of the day rather than at the beginning due to deformation and swelling.
- Fit shoes to the longer foot with a toe clearance of 9-12mm at the longest toe.

It should be noted (Goonetilleke 2003) that proper shoe fitting should consider heel-to-toe length of the foot as well as the arch length. If differences exist, the correct shoe size is determined using the larger of the two measures, arch length or overall heel-toe length. If the arch length is larger than heel-to length, the shoe size is chosen to correspond to the arch length. Similarly, if the heel-toe length is larger than the arch length, the shoe size is supposed to correspond to the heel-toe length as otherwise the shoe will be too short. The principle of fitted footwear for diabetic patients was looked into by Jeffcoate and Macfarlane in 1995. They explained in their research paper that the principle of fitted footwear is to provide a shoe which is deep enough and broad enough, but floppy. They point out that the materials for making the shoe, especially the upper should be soft, and there should be good instep support.

It is recommended (Tyrrell and Carter 2009) that both modular and bespoke footwear should be made to fitting stage- without permanent soles and heels attached. At this point, alterations to length, width, and girth can easily be made. To ensure that the shoe fits well, it is advisable to have subsequent fittings, because the moment the sole and heel have been permanently attached, the footwear cannot be altered.

2.11.2 Footwear Fastenings.

Another important consideration in the choice of shoe style for diabetic feet is in the area of how to manage shoe fastenings. Some people find it difficult or impossible to fasten their shoes for a variety of reasons. They may be physically incapable of reaching their feet because of obesity, paralysis, arthritis, may be unable to see sufficiently well; they may have lost one or more fingers, or they may have lost a hand or an arm; or lack of co-ordination, and many other reasons too many to mention here. One obvious solution to the problem of fastening shoes is the use of ‘slip-on’ shoes but, they are not wholly satisfactory. They are limited to certain types and ages of people and to certain occasions (England 1973).

Some of the common footwear fasteners used are; Zip fasteners, laces, a transverse strap and buckle, Velcro. Velcro, which looks like two opposing strips of coarse velvet and adheres on impact, may be used by people living with diabetes. One of the great advantages of using Velcro is that it can be made to work without any precision of touch, even by means of the pressure of one foot upon the other (England 1973).

2.12.0 Diabetic Socks and Orthoses.

2.12.1 Diabetic Socks.

There are different types of socks available in the market, but people with diabetes need to select good socks that fit well. Regular 100% cotton or wool socks are criticized for being too tight on the foot and thus reducing circulation. Additionally, many argue that the coarse seams may rub the foot too firmly thus causing blisters and calluses to emerge (Porter 2006). Porter explains further that diabetic socks on the other hand, are made from a combination of cotton, acrylic, nylon, and elastic fibers. These are designed to maximize comfort and cushioning for the wearer while keeping the foot dry and cool. Carmel and Edelman, (2005) recommend that diabetic patients should wear clean cotton socks every day that are soft and that do not have thick seams, creases, or holes that could rub the skin. In addition, the socks should be seamless and loose (Torreguitart 2009).

Information from the internet shows that a new range of soothing socks for diabetes is available for diabetes patients (www.feetforlife.org/cgi-bin/item.cgi). The socks are made with 98% super soft cotton and 2% lycra. It is explained that the socks feel extremely light to wear and are not held in place by fine ribbing and non-constricting tender grip tops. Many people living with diabetes suffer from swelling of the feet and ankles, so the lightweight sock is available in extra roomy as well as normal width fittings.

According to a 1993 study conducted by Murray, and other group of researchers, diabetes socks have a high level of patient satisfaction when worn with suitable shoes, and may be an acceptable and inexpensive addition to existing methods of protecting the high-risk insensitive diabetic foot.

> "Choosing quality diabetic socks addresses moisture in the shoe environment, friction, pressure from sock seams, or wrinkling and bunching, all of which can potentially be a source of irritation for diabetic or sensitive feet. Diabetic socks are the first layer of protection provided by quality diabetic socks made for sensitive feet." Knit-Rite, Inc (2010) www.diabeticsocks.com/

Feldman and Davies (2001) argue that people with diabetes who have "normal" feet should be able to wear whatever socks they find to be comfortable. But the socks should fit well without constricting cuffs, lumps or uncomfortable seams. On the other hand, Veves and other scientists (1990) state that socks designed to reduce pressure stress on the diabetic neuropathic feet is effective, and continues to be so for a considerable period of time. They added that commercially available sports socks may also have a place in the management of the diabetic insensitive foot.

2.12.2 Orthoses

Foot orthosis is a device that is placed inside footwear that acts as an interface between the footwear and the weight bearing surface of the foot with the goal of correcting foot problem through providing support for the foot during weight bearing (Muogboh 2000).

2.13.0 Social, Cultural and Eco- Design Issues.

2.13.1 Social Considerations.

Social consideration plays important role in the design and marketing of products particularly in modern society. Dant (1999 p.13) states that 'all objects are social agents in the limited sense that they extend human action and mediate meanings between humans.' He explains that it is culture that specifies how we make sense of shapes, colours and how we make use of and live with things.

Rielo (2006) rightly points out that social and political dynamics are important elements in the way products are designed or conceived, marketed, accepted and used. And on the issue of the design and marketing of assistive products, Baines (2010) stresses that if assistive technology products are marketed directly at the elderly or disable persons, there may be strong resistance by the consumers who do not wish to consider themselves as people with special needs. Thus, any design of a product that encourages stigmatization must be avoided.

2.13.2 Cultural Considerations.

It is important to note that footwear needs can vary in different cultures. Nathan and Singh (2008) revealed that there is a marked difference in footwear habits in the developed countries compared to that of developing or less developed countries. They pointed out that in the developing world, people tend to wear sandals and slippers and some do not wear shoes at all due to poverty or religious reasons. These cultural differences can have great influence in the manner in which footwear is design in different societies.

Sticking to traditional, familiar form in the design of products by designers makes it more acceptable to the consumers. Travis (2009 p.2) said that when a product 'is built into a familiar form, it becomes more appealing to the consumer'. This shows that design can be a powerful tool in getting consumers to accept new things and ideas. In post-modern society, footwear design should be based on the principle of good design outlined decades back by Read (1966) taken into critical consideration the element of 'shape' or 'form'. Therefore, when it comes to the issue of footwear design for impaired foot, the style of the product should be created in an innovated way but bearing in mind social and cultural tastes and values of the consumers.

2.13.3 Eco-Design Issues.

According to Weib (1999), there are approximately 40 different materials that are used to make a pair of shoe. The chart below (fig. 2.14) gives material composition in average shoe.

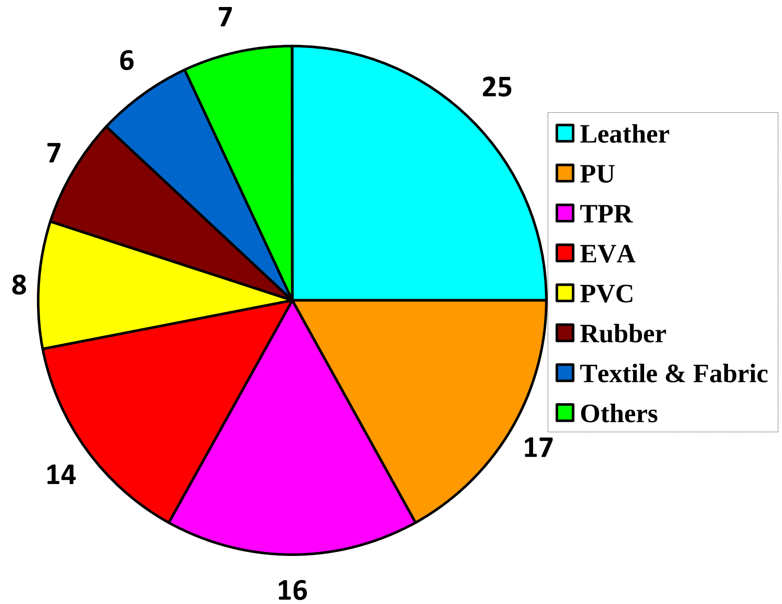


Fig. 2.15 Material composition in average shoe (%). Source: Rahimifard (2007 p. 2) Centre for Sustainable Manufacturing and Reuse/ Recycling Technologies.

We can deduce from figure 2.14 that the widely use materials for shoe manufacturing are; leather, PU (polyurethane), Thermoplastic rubber (TPR), and Ethyle Vinyl Acetate (EVA). For the fact that wide range of materials are used in footwear manufacturing (see fig. 2.15), it would be necessary to briefly outline some basic sustainability issues here.

The term sustainable design denotes design of products that have low or no environmental effects. There are so many terms that are recently used to describe this type of design. Some of the terms commonly used are: green design, eco-design, eco-effective design, environmentally conscious design, holistic and environmentally friendly design, design for the environment etc. Mclennam (2004 p. 6) defined green design or sustainable design as ‘a design philosophy that seeks to maximize the quality of the built environment, while minimizing or eliminating negative impact to the natural environment’. He further explained that the term is used as an umbrella term to explain a number of strategies, components and technologies that would lower environmental impact while in many cases improving comfort and overall quality.

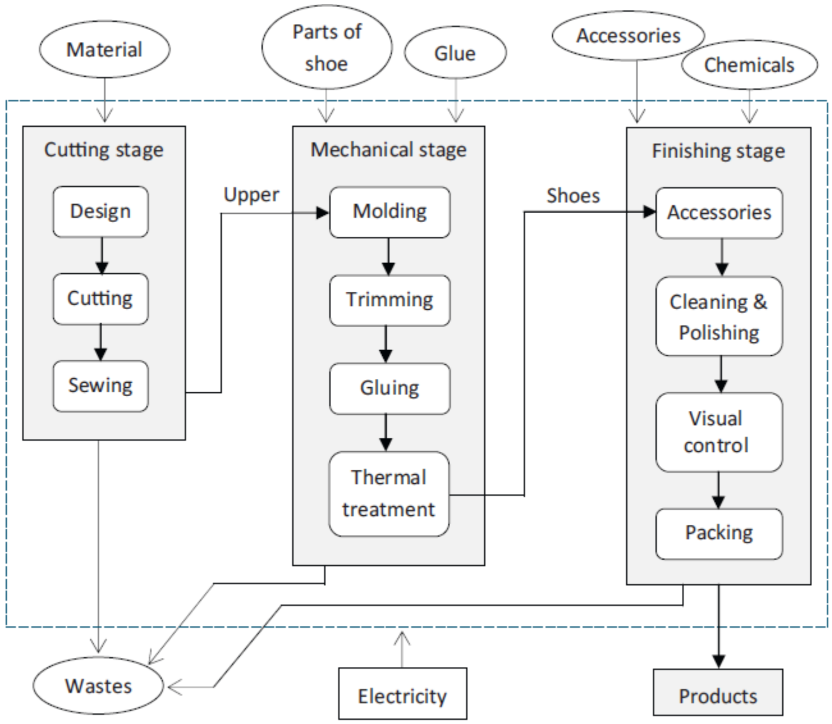


Fig. 2.16 Flow sheet of the shoe making factory (Herva et al. 2011, p. 1878)

According to UNESCO (2002, http://www.unesco.org/en/social/.), the philosophy of green design is to design products/ services that would meet the needs of present generations without compromising the ability of future generations to satisfy their needs. And Kofi A. Annan (December 2006), former UN Secretary General states, 'we thrive and survive on the planet earth as a single human family. And one of our main responsibilities is to leave to successor generations a sustainable future.'

The approach to solving environmental problems varies from place to place. The Climate Change Act 2008 makes the UK the first country to cut carbon emissions. Part 1 of the Act sets a target of at least 80% reduction of carbon than the 1990 baseline by 2050 and part 5 gives the general regulations for waste reduction, renewable transport fuel obligations, etc. www.opsi.gov.uk. The Environmental Protection Act 1990 by the U.S.A provides environmental regulations on air, land and water quality. The Act also sets regulations for prohibition on unauthorized or harmful deposit, treatment or disposal etc of waste. Green design is fast becoming a mandate with serious legal implications as shown by the EU's REACH directive, which regulates the use of chemicals in finished products sold in the EU (Going-Green 2009). Nigeria as a developing nation applies 'anticipative and preventive' strategies that avoid expensive and intensive environmental control measures as a policy (Adewoye 1998)

The UN delegations at World Summit in 2002 at Johannesburg (Browne 2002) agree on banning the use and production of toxic chemicals, hazardous to human health and environment, by 2020. Chemicals that are facing global bans include parathion, lindane, lead additives for petrol, pirimiphos.

The EU regulations on landfill restrictions and the UK Landfill Allowances and Trading Scheme Regulation (LATS) introduced in 2004 determine the amount of certain waste type that is regarded as biodegradable municipal waste. According to Rahimifard (2007. p.7), 'these biodegradable percentages range from paper, cardboard and vegetable oils (potentially 100% biodegradable) through to footwear, furniture and textiles (50% biodegradable), and batteries, glass, and metal waste (0% biodegradable).'

These regulations must guide the operations of all footwear manufacturers and retailers as government would not spare any corporation that carries out business contrary to the provisions of these regulations. For example, Brantano, a major UK-wide footwear retailer has been recently ordered to pay over £30,000 in fines and costs of failing to comply with some regulations (Brass 2010 www.greenwisebusiness.co.uk/news/environment/). Three types of sustainability concepts could be explored by the footwear designers as outlined below.

1. Design for Disassembly

Design for disassembly can be explained as a design strategy that takes into consideration the future need to disassemble a product for repair, refurbish or recycle (Diener 2010). Footwear is designed and built using different materials that require different methods of end-of-life handily. The idea of design for disassembly is to design and make shoes in a way that the different components (the sole, insole, and the upper) could be detached after use so that the different parts could be recycled easily. The principle removes the 'difficulties in retrieving and re-using these materials' (Mackenzie 1991 P.71). Example of this type of footwear is given in figure 2.10.

Fig. 2.17 Example of footwear designed for disassembly. Available from: http://design.gamil.com/2010/02/meld-footwear

2. Design for Durability

Materials which are durable for example leather can be used to make upper and insole of shoes and PU which is a good recyclable material, could be used for the sole of the shoe. These materials are very durable and can be recycled when they have come to the end of their useful life (Rahimifard 2007).

3. Recycling or Cradle-to-Cradle

In a cradle-to-cradle conception, eco-effective materials and methods of manufacturing are explored. The concept has 'materials as one of its key areas (others are reutilization, water use, energy consumption and social responsibility). With a worldwide production of 20 billion pairs of footwear in 2010, there is a great magnitude of challenge when dealing with the final disposal of footwear products. But processing, use of raw materials and components, and end-of-life disposal are the main areas of concerns in the footwear industry (Madhero 2007; Stephenson 2009; Jacques & Guimaraes 2012). For example, in the tanning of hides/ skins (a material commonly used for shoe making) vegetable tannins and recycling of beamhouse (pre-tanning) liquors are being explored to make leathers and shoes that have low impact to the environment. Leather International, Sept. 2009. www.leathermag.com/ . McDonough (2002. p. 99) pointed out that 'to eliminate the concept of waste means to design things-products, packaging, and systems-from the very beginning on the understanding that waste does not exist'. The concept of the cradle-to-cradle or recycling (look at fig. 2.17) is a welcoming idea for the footwear industry because it would give more prospects for the industry than the current way of making things-cradle to grave.

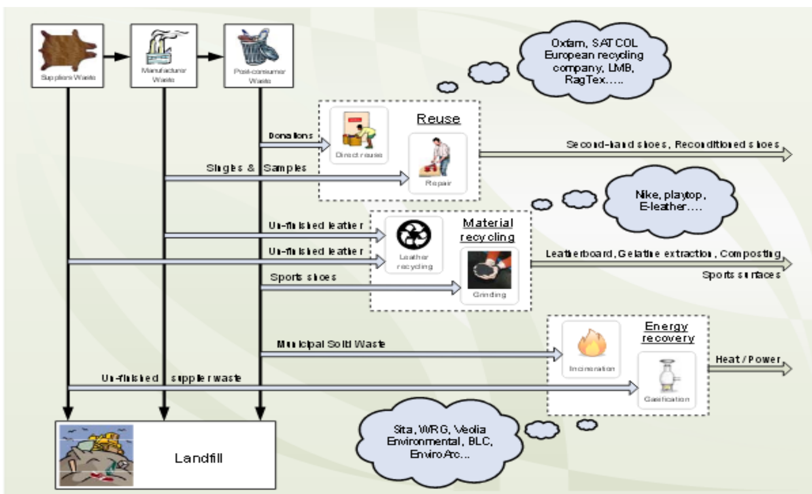


Fig. 2. 18 Recycling solutions (Rahimifard et al 2007 P. 5).

2.14 Footwear Prototyping.

Development and manufacturing products such as footwear can be facilitated by using prototyping techniques. Footwear prototyping helps to reduce the bottom line cost of research and development, but the prototyping itself is a costly feature and prototype design and production can add considerable expense to a project. Two essential factors have been identified (Jimeno-morenilla, 2011) as determinants for a shoe model to be fully valid in the process of footwear design and manufacture: these are –fashion and comfort. The first involves the definition of an attractive model that meets the expectations of the customer. The second aspect to consider is the comfortability characteristics of the product.

Using 3D technology to produce footwear prototypes is one of the techniques that is used by the footwear industry to make footwear prototypes. The technique has numerous advantages, such as being able to control the number of prototypes produced, fabrication materials, and production schedules. Rapid prototyping helps to eliminates many of the cost associated with conventional prototype production, including expensive tooling, redesign cost, and delayed product development. The technique streamlines the process of prototyping and cut costs where design changes have to be made. Comparing the production cost of footwear prototyping with traditional tooling, footwear prototyping using three dimensional (3D) technology is the most cost effective method (Jimeno-morenilla 2011).

2.15 Diabetic footwear market.

Marketing from the view point of manufacturer (Adidas Group 2009) is about creating innovative concepts and determining how to make products successful in the market place. For the manufacturers to make their products successful in the market place, they must have a way of controlling and monitoring the supply of all the materials used in manufacturing the products and how the designers must be able to standardize their patterns.

Currently, 285 million people are affected with diabetes worldwide and the number is expected to grow to 438 million by 2030. And the largest age group currently affected by diabetes is between 40-59 years old (World Health Organization 2010; International Diabetes Federation 2009; and World Footwear 2008). It therefore means that diabetic footwear has become a growth market.

Price plays an important role in the footwear market. It is observed that the general trend for shoe production has been for production to decline in developed countries and increase in developing countries where the labour cost is more advantageous (Turrell 2009; & Price 1999).

With its abundance of cheap labour, Asia, is by far the largest footwear producing region. It has 55% of the world's population and it is expected that Asia's share of the World footwear production will continue to expand, but at a slower rate. South Korea and Taiwan used to dominate production in the region, but as their labour costs increased, there was a significant shift to other countries such as China, Indonesia, Thailand and Vietnam. But it is expected that there will be an increased competition from developing countries in other regions such as Africa and Eastern Europe. However, there are serious economic and political pressures in both these regions that are currently preventing the expansion of the footwear industries in those regions (Price 1999).

The information made available by SATRA's Technology Centre (Price 1999) has indicated that in Western Europe, Italy has been the most successful country where footwear manufacture and exports are both expanding over the past few years. Apart from Spain and Portugal, most other countries in the region show a continued decline in manufacture which is expected to continue due to labour cost and other restrictions (for example stringent environmental legislations).

The footwear market situation in Central and South America is said to be volatile due to rapid changes in the political and economic climate of the region and is expected to remain so for the foreseeable future.

2.16 Chapter Summary.

The literature on diabetes and diabetic footwear as reviewed and analyzed above has provided an extensive range of information concerning diabetes, and the particular foot problems associated with diabetes. The assessment of the literature has also revealed the need for diabetic patients to use or wear special footwear that will serve the important purpose of protection and support allowing for individuals to perform their activities of daily living. The basic information required to design and construct footwear that fits diabetes foot appropriately was also developed as a consequence of analyzing research evidence presented in the literature review.

Chapter 3: Data Collection with Questionnaire

3.1 Introduction.

There is evidence that lack of patient knowledge about foot care, uncontrolled diabetes and the use of improper footwear are key factors contributing to most devastating preventable foot complications. However, the design and manufacture of diabetic footwear based on an understanding of patients' expectations and perceptions of footwear are not often considered. Therefore, for a complete view of the role of diabetic footwear in the prevention or management of diabetic foot complications, the opinions of people suffering with the disease was sought in this study through a questionnaire survey.

Information on the outcome of the questionnaire survey carried out in Nigeria among diabetic patients is provided in this chapter. The survey was designed to access a range of data from people with diabetes that provided the researcher with useful information for developing design concepts for diabetic footwear. The research participants shared their thoughts and experiences on factors that would affect the design and construction of diabetic footwear. Therefore, this chapter provides key information on diabetic foot problems and the important factors to consider for designing diabetic footwear from the viewpoint of people suffering with the disease. The chapter ends with an analysis and discussion of the outcome of the survey.

3.2.0 Aim/ Objectives of this Chapter

3.2.1 Aim

The aim of this empirical research was to gather information from diabetic patients mainly about foot problems, foot care and their preferred type of footwear in order to develop an appropriate diabetic footwear design frame.

3.2.2 Objectives

- To understand the nature of diabetic foot problems.
- To investigate the type and feature of footwear often used by diabetes patients in Nigeria.
- To study diabetes patients' preferred footwear materials.
- To generate data for developing appropriate footwear design(s) for people suffering with diabetes.
- To identify areas that would require further investigation.

3.3 Protocol for the survey.

Figure 3.1 gives a summary of the protocol followed to carry out the questionnaire survey.

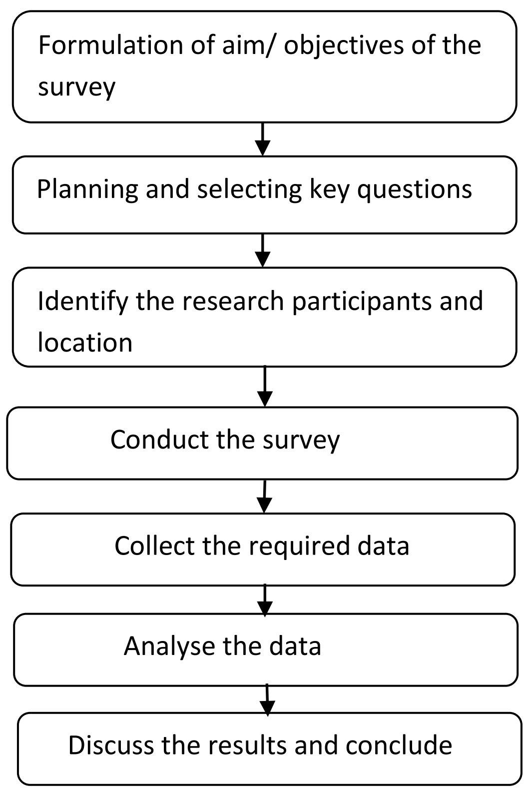


Fig. 3.1 Protocol for questionnaire survey.

3.4.0 Method

In this study, a questionnaire was formulated based on key objectives of the study. Questionnaires are considered to be one of the most widely used primary data gathering techniques. It is a research tool through which people are asked to respond to the same set of questions in a predetermined order (Gray 2004). It is also a technique that is used to seek views and perspectives of respondents. Data collected by questionnaire may be either qualitative or quantitative. However, questionnaires do lend themselves more to quantitative forms of analysis because they are designed to collect mostly discrete items of information, either numbers or words which can be coded and represented as numbers (Blaxter et al. 2010). It has been pointed out that surveys and experiments are probably the main vehicles of quantitative research (Bryman 1996). The data gathered in this chapter are mainly quantitative. Nonetheless, to ensure that other vital information not mentioned in the questionnaire would be identified, certain qualitative data were also gathered and interpreted. This approach was used in order to have a better understanding of different areas of the study. Moreover, it has been reported that much research uses a combination of methods for data collection to strengthen a study by providing different types of data (Crouch & Pearce 2012; Flick, et al. 2004; Black 1999).

During the formulation of the questionnaire, it was agreed that a multiple-choice questionnaire would be the simplest and quickest way of getting the main information required. In some cases, however, respondents were requested to rank certain elements or features based on their preference, and only one or two questions were open-ended (the detailed questionnaire is provided as appendix IV). To ensure that the research questionnaire was well structured and that important items were included in the survey tool, the questionnaire was divided into four sections. The first section explores the background information of the respondents. The second section evaluates diabetic foot problems and foot care services available to the respondents. The third section examines foot problems and the role of footwear among people suffering with diabetes. In the fourth section, information on footwear fitting/ features is gathered. The design of the questionnaire was in accordance with the literature (Burns 2000) that suggests a good questionnaire should have four sections: The introduction, warm-up questions, the body of the study, and demography questions. The literature further explains that many researchers find it most appropriate to place demographic questions, concerning the sex of the respondent, socioeconomic status, age and so on, at the beginning of the questionnaire. The reason for this is that while one of the warm-up questions might upset the respondent and lead to negative response or to discontinue participation in the study, demographic questions do not usually upset and lead the respondent well into the questionnaire.

For validation of the questionnaire, it was decided that a pilot survey should be carried out prior to the actual study (see sub-section 3.4.3).

3.4.1 Research Participants.

The survey was carried out at different hospitals in Kaduna State, Nigeria from December 2012 to March 2013. The researcher and/ or his research assistants approached each diabetic patient in the hospital waiting room and asked them to complete the questionnaire while waiting to see the doctor. An oral explanation of the research was given to each participant in addition to a written explanation that accompanied the questionnaire. Questionnaires were not given to patients who refused. In most cases, completed questionnaires were returned to the researcher immediately. Overall, 180 questionnaires were given out to people living with diabetes and 164 were collected back, but 8 were rejected or excluded from the analysis because they were not properly completed. Therefore, **156** (75 male and 81 female) filled questionnaires were analysed and the results are presented in sub-section 3.5.

3.4.2 Ethical consideration and Standard Operating Procedure (SOP).

Ethical approval for this study was obtained from De Montfort University, Leicester, the Ministry of Health, Kaduna State and Ahmadu Bello University Teaching Hospital, Zaria, Nigeria (see appendices XIa, XIb, & XIc). Participants at the beginning of the study were given information on the nature of the survey, the anonymity and confidentiality of personal data and the participants' right to withdraw from the study at any time. Hence, the participants entered into the research voluntarily and with adequate information. No one was subtly coerced or unduly influenced to participate in the research.

A Standard Operating Procedure (SOP) was designed for the study (see appendix VII). It consisted of structured questions that helped the researcher to identify the locations of the research participants. In addition, it was also used to guide the researcher in step by step conducting of the survey.

3.4.3 Pilot study

The pilot study was carried out to ensure that the survey tools could determine the research area of interest reliably and validly when used for the real survey. The specific objectives are:

- To obtain professional feedback about the initial version of the survey materials
- To collect preliminary information from the proposed research participants
- To identify ways to improve the survey items
- To identify ways to administer the actual survey to participants effectively.

An initial investigation or pilot survey is an important step to determine the next step of the survey process that should be undertaken prior to administering an actual survey to the research participants. It is described as a mini piece of research that is used to ensure that the questions set could be easily answered and the tools to be used actually work (Etchegaray & Fischer 2011; www.wiki.aswers.comm 2013). A pilot survey is a great deal of work, but if it is done properly, many complications often not considered are handled at this stage and makes the following research much easier. Even though the specifics of the pilot survey vary among researchers, the goal is the same: that is, to ensure that the items can measure the area of interest reliably when used in real situations. In this work, a structured questionnaire for diabetic patients was prepared and administered at some hospitals where the actual survey was planned to be conducted in order to see whether the questions would be appropriate to get the responses the researcher was aiming at receiving. The initial investigations helped the researcher to make changes to the survey items. The key changes that were made were:

i. One view of the initial foot image (see appendix VIII) that was used for the pilot survey was considered inadequate to be used to gather the required data from the respondents about their foot problems. Therefore, the foot image was re-presented in 3 views during the full survey (as given in fig. 3.3, 3.5 & 3.7).

ii. The questionnaire was not initially divided into sub-sections, but it was observed during the pilot study that the respondents did not find it interesting to fill in. So, the final questionnaire was divided into sub-sections (see appendix IV) to make it easier for the respondents to complete and for the researcher to analyse.

3.5.0 Results

The individual outcomes of the questionnaire survey were coded, analysed and the findings are presented in this section mainly in the form of tables and charts.

Table 3.1. Participants' personal information.

Enquiry		Males % (n=75)	Females % (n=81)	Overall % (n=156)
1. Sex		48	52	100
2. Age (years)	≤ 20	0	0	0
	21-35	08	05	06
	36-50	24	42	33
	51-65	49	38	44
	≥ 66	19	15	17
	Mean	55.3	52.9	54.1
3. Occupation	Employed	34	28	31
	0wn business	23	31	27
	Unemployed	03	03	03
	Retired	23	05	14
	Student	0	0	0
	Farmer	15	0	07
	housewife	NA*	33	18
4. Residency	Rural	16	22	19
	Urban	84	78	81
5. Type of diabetes	type 1	07	04	05
	type 2	36	20	28
	Do not know	57	76	67
6. Duration of living with diabetics	≤5yrs	45	38	41
	6-10yrs	25	38	32
	11-15yrs	15	15	15
	16-20yrs	10	06	08
	≥21yrs	05	03	04
	mean	7.7	9.0	7.5

*NA-Not Applicable

The background information about the research participants presented in table 4.1 has provided data on the participants' sex, age group, occupation, residency, type of diabetes and duration of living with the disease.

The findings are shown as percentages with n=156 for both males (48%) and females (52%) participants. The findings indicate a wide spectrum of different age groups who are suffering with the disease. Half of the participants are 51-65 years and those that are between 36 years and 50 years accounts for 31% of the respondents. Therefore, eighty one percent of the participants are less than 65 years of age. When the patients were asked how long they have been living with the disease, 41% indicated that they have been living with diabetes for less than 5 years and 32% state that they have being suffering with the disease for 6-10 years. Only 4% of those that participated in the study reported that they have lived with diabetes for over 20 years. The mean age of the duration of living with the disease for both male and female participants was found to be 7.5 years.

Table 3.1 has also shown that up to 31% of the respondents were employed and 27% are engaged in their own businesses. Eighteen percent of those that participated in the study were housewives. The majority (81%) of the patients involved in the survey live in towns, whereas only 19% live in rural areas. This is because most of the survey was carried out in urban hospitals.

When patients were questioned about type of diabetes they were suffering with, up to 67% reported that they did not know, while 28% state that they were suffering with type 2 diabetics and only 5% reported that they have type 1 diabetes.

Table 3.2. Diabetic foot problems and foot care.

Enquiry	Males (n=75)		Females (n=81)		Overall (n=156)	
	Yes (%)	No (%)	Yes (%)	No (%)	Yes (%)	No (%)
1. Feet have been checked by health professional	70	30	71	29	70	30
2. Ever reported numbness or pain in the feet to a doctor	59	41	62	38	61	39
3. Suffering with foot problems like ulcer, blisters, wound, etc.	44	66	35	65	40	60

It was discovered from the survey that the patients' feet are not checked ordinarily by the doctors except if they have complained of pain or any other foot problem. Table 3.2 gives some insight into the level of foot problems diabetes patients experience. The results in the table shows that 70%, 61% and 40% at one time or another had their feet checked by a health professional, reported pain in the feet, and suffered with foot problems like ulcers, respectively.

Figures 3.2 to 3.7 provide findings on the areas or parts of the foot patients mostly experience foot problems. Three views (plantar or the sole, dorsal/ lateral and dorsal/ medial) of the foot were presented to the research participants to indicate the particular area or location they have foot problems like pains, wound, ulcers, gangrene etc, if they have any.

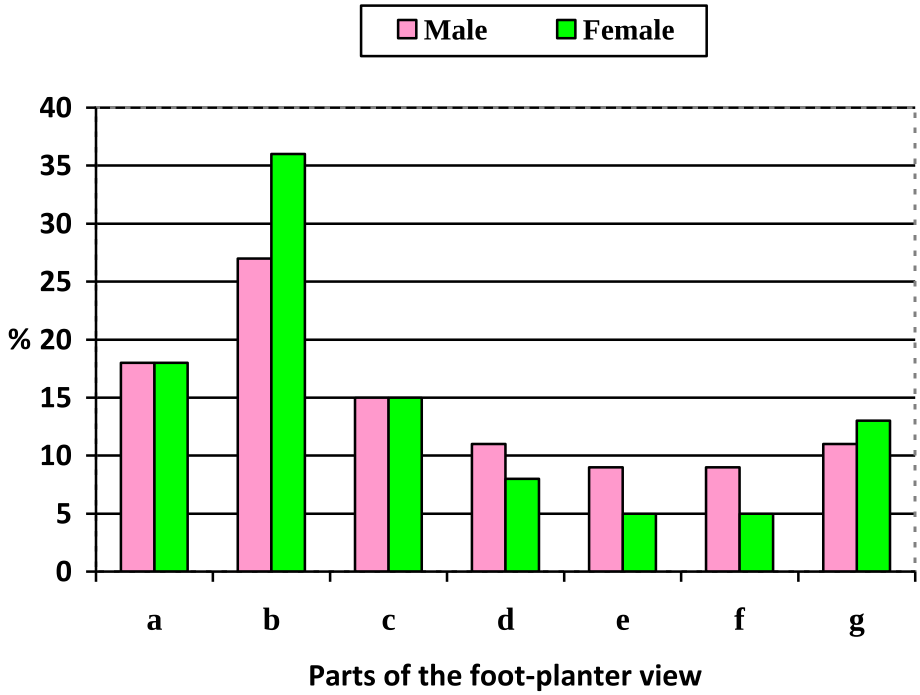
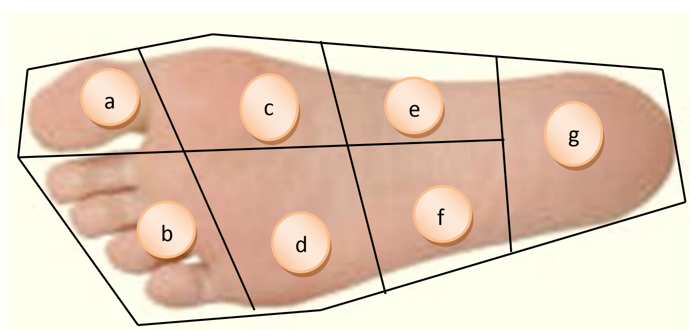


Fig. 3.2. Foot problems located on the plantar (refer to fig. 3.3).



Note:
(**a**) Big toe
(**b**) phalanges (**c**) 1st MTP joint
(**d**) 2nd -5th MTP joint
(**e**) Plantar/ medial (In-between heel & MTP location)
(**f**) Plantar/ lateral (In-between heel & MTP location)
(**g**) heel

Fig.3.3 Plantar views of the Human foot.

Figure 3.3 shows that foot problems located at sole or plantar part of the foot occurred mostly at location ‘b’ with percentages up to 36% for females and 27% for males. The second location with very significant percentage of foot problems is location ‘a’ which is up to 18% for both males and females. Locations ‘a’ and ‘b’ are the distal part of the foot or the phalanges.

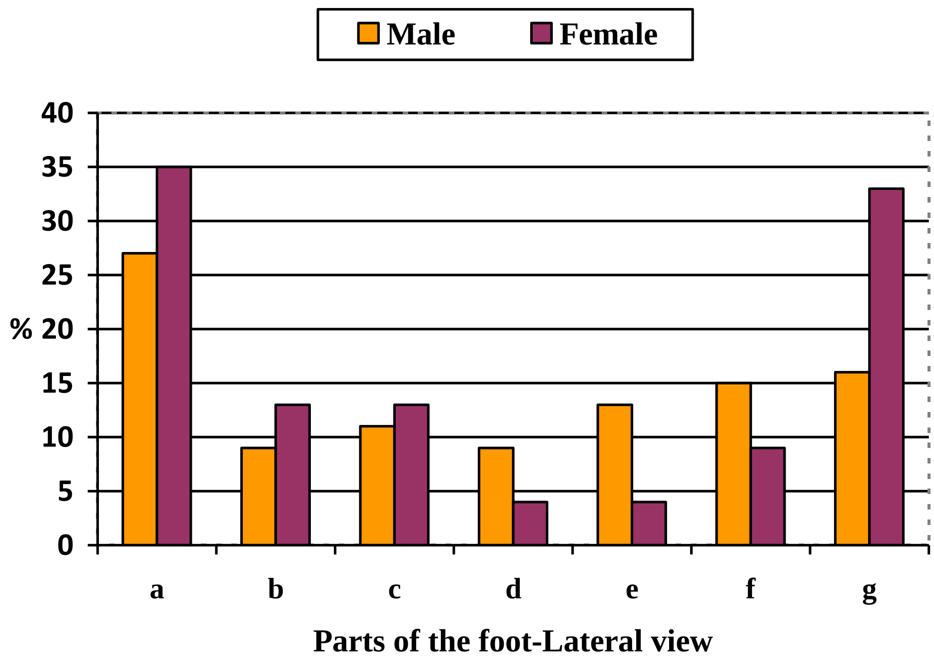
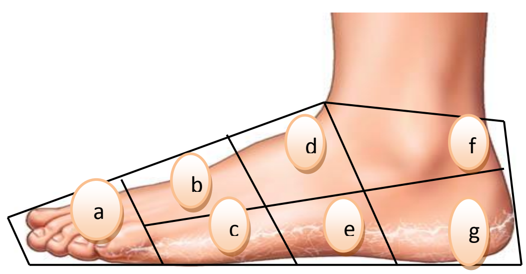


Fig.3.4. Foot problems located at the lateral part of the foot (refer to fig.3.5)



Note: (**a)** Toes **(b)** MTP joint (dorsal) **(c)**MTP joint **(d)** In-step **(e)** Lateral (location between heel & MTP **(f)** Ball joint **g.** heel.

Fig. 3.5 lateral view of a human foot.

The top two locations of the foot in regards to the dorsal/ lateral view mostly affected with foot problems are locations ‘a’ and ‘g’. Location ‘a’ with 35% and 27% foot problems for both female and male respectively represents the entire phalanges. Secondly, 22% foot problems among female participants were located at the heel, while 16% of males indicated that they experience foot problems at the heel.

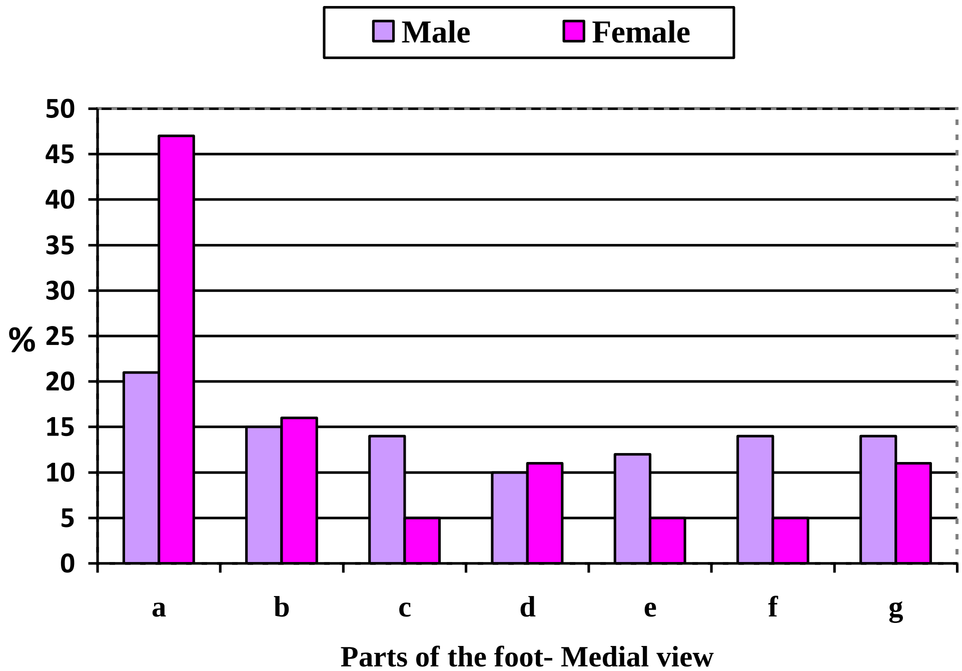
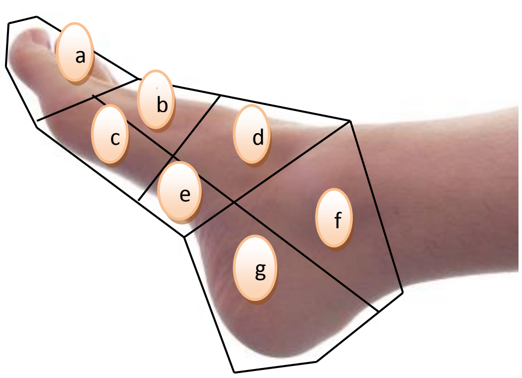


Fig. 3.6. Location of foot problems on the dorsal/medial side (refer to fig. 3.7)



Note: **(a)** Big toe/ other toes **(b)** MTP joint **(c)** MTP **(d)** In-step **(e)** Medial (location between heel & MTP joint **(f)** Ball joint **(g)** Heel.

Fig. 3.7 Medial view of a human foot.

This survey also provided information on foot problems located at the dorsal/ medial view of the foot. Figure 3.6 clearly shows that the highest percentage of the problems occurred at the phalanges. Almost half (47%) of the foot problems experienced by the female subjects were experienced at the phalanges and up to 21% of the problems were experienced at the same location by the male participants.

Table 3.3. Areas of the foot with particular sensitivity or pain caused by the use of inappropriate footwear (refer to fig. 3.3, 3.5 & 3.7 to view the different foot locations).

Foot Location	Plantar View	Lateral View	Medial View
	Male (Female)	**Male (Female)**	**Male (Female)**
a (%)	16 (11)	22 (17)	26 (15)
b (%)	23 (26)	08 (15)	10 (14)
c (%)	15 (14)	08 (15)	13 (15)
d (%)	08 (12)	19 (13)	13 (14)
e (%)	14 (14)	08 (12)	09 (14)
f (%)	08 (09)	16 (15)	13 (13)
g (%)	16 (14)	13 (16)	16 (15)

The highest values (26% & 23% for female and male respectively) in table 3.3 are found at the plantar (at location 'b'). Looking at data for the dorsal/ lateral view, location 'a' gives the highest percentages (22% and 17%) for both male and female participants respectively. Location 'f' with values up to 16% for male and 15% for female is another location that should be noted. For the dorsal/ medial part of the foot that most of the discomfort or pains were experienced by the male participants, location 'a' has the highest value (26%). The values from one location to another did not vary significantly.

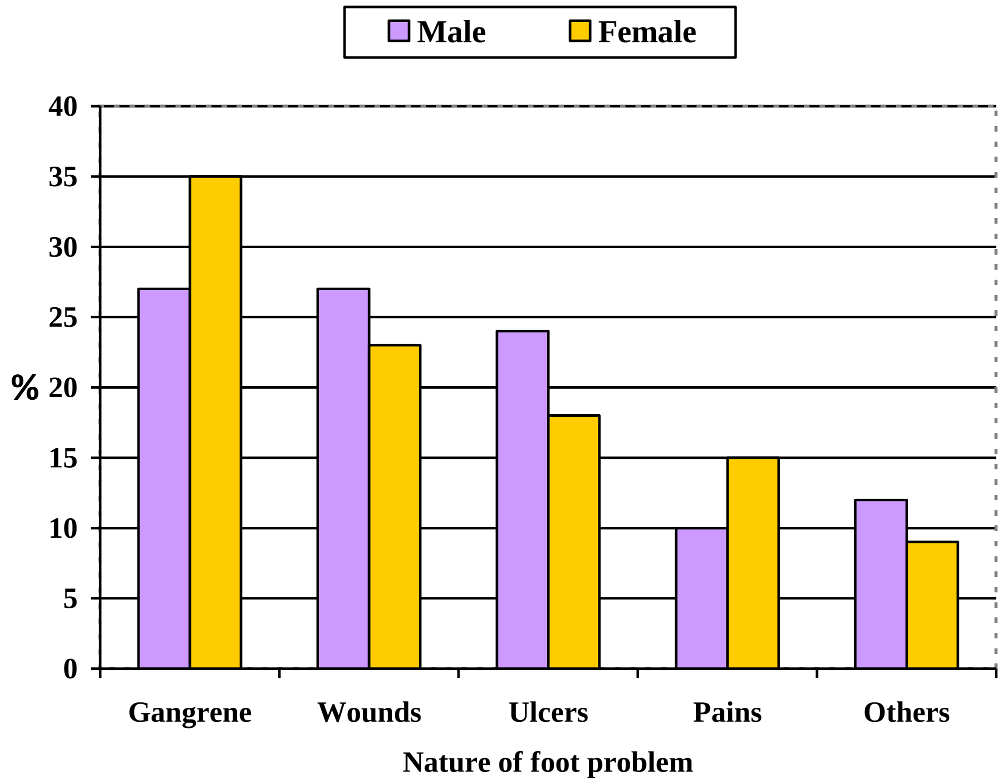
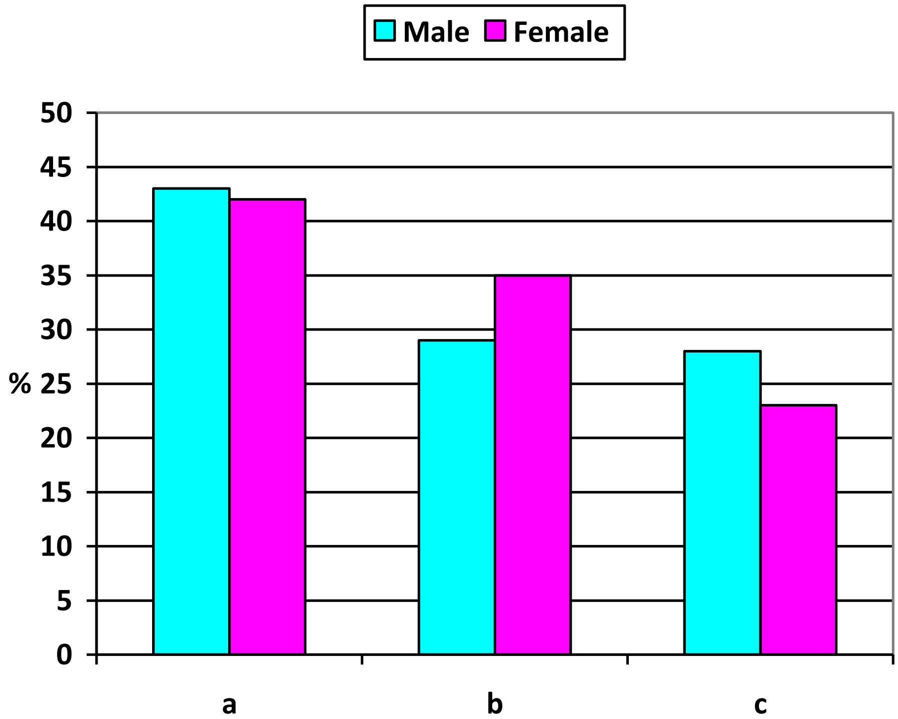


Fig. 3.8 Nature of foot problems among diabetic patients.

Most of the participants that reported of foot problems indicated that they had at least one of the conditions mentioned in figure 4.8 above. However, the presence of wounds ranked highest at 31% for females participants, whereas wound and gangrene ranked highest at 27% among males participants. Twenty four percent of both male and female participants reported that they had foot ulcers. Gangrene was found to be more prominent among female patients with up to 35% reported cases. On the other hand, the cases of severe pains at the foot were more common among the male participants.



a. Shoes are too tight; **b.** Shoes are rubbing feet; **c**. Shoes are pinching feet

Fig. 3.9 Causes of pain/ injury as a result of wearing inappropriate footwear.

Interestingly, figure 3.9 gives vital information about causes of pain/ injury for patients as a result of wearing inappropriate footwear. The findings indicate that almost half (43% & 42% for males and females respectively) of the cause of pain or foot injury for participants was as a result of wearing shoes that are too tight. Other reasons with significant impact for causing foot pain and injury due to using footwear were be attributed to shoes rubbing feet (up to 35% for females and 29% for males) or pinching (28% and 23% for males and females respectively) the feet of the wearer.

Table 3. 4. Footwear Fitting/ Features.

Enquiry	Male		Female		Overall	
	Yes (%)	**No (%)**	**Yes (%)**	**No (%)**	**Yes (%)**	**No (%)**
1. Regular shoes not able to accommodate patients' feet due to foot problems	38	62	30	70	34	66
2. Shoes need modification in order to accommodate feet well	28	72	34	66	31	69
3. Patient walk without shoes or barefoot sometimes	35	65	42	58	38	62
4. Find it difficult to put on shoes or to take off shoes	31	69	28	72	29	71
5. Wear shoes without socks	66	34	75	25	70	30
6. Comfortable with own shoes	76	24	86	14	81	19
7. Patient knows his/her correct shoe size	92	08	92	08	92	08
8. Patient needs different sizes of shoes for left and right feet	12	88	06	94	09	91
9. Receive information about type of footwear to wear most often	25	75	34	66	25	75
10. Willing to use footwear with extra insert materials as insoles	78	22	83	17	81	19
11. Willing to buy footwear that could cost double the amount usually spent on shoes, if recommended by a doctor.	88	12	80	20	84	16

The aim of this section was to investigate the experience of patients on the use of their footwear in terms of fitting and their willingness to use extra inserts materials. Secondly, it was to find out if they received information about the type of footwear they should use often and their willingness to use or buy shoes that may be recommended to them by their health care providers.

The first item in table 3.4 gives information on participants that regular shoes are unable to accommodate their feet due to foot problems. It can be observed from the findings that 34% of those that participated in the study cannot wear regular shoes. When asked the reason why they could not use regular footwear, one of the respondents said; "*My ulcered foot caused by diabetes has deprived me from wearing any type of shoes I like."* The second item on the need to modify patients' footwear in order to accommodate their feet well gives a very similar percentage (31%) to item one (those that reported that regular shoes cannot accommodate their feet).

Looking at item 3 in the table above, a significant number of patients (38%) sometimes walk without shoes or barefoot, a situation that is not recommended for diabetic patients because their feet need to be protected always. When asked if they find it difficult to put on shoes or take off their shoes, 29% of those that participated in the survey reported that they find it very difficult to put on or take off their shoes.

It has been recommended that diabetic patients wear clean cotton socks every day that are soft and that do not have thick seams, creases, or holes that could rub the skin (Carmel & Edelman 2005). It can be observed from the findings shown in table 3.4 that only 30% of the responded reported that they wear shoes with socks, whereas the majority (70%) do not wear socks at all.

The survey also investigated the knowledge of diabetes patients about their shoe size. The findings indicate that 8% did not know their correct shoe sizes and 9% reported that they needed different sizes of shoes for their right and left feet.

It has been discovered from this study that only 25% of the respondents receive information about the type of footwear they should wear most often while up to 75% do not receive information on the issue. Another interesting finding presented in table 3 is willingness of the patients to buy shoes that would cost them double the amount they usually spend on footwear if recommended by a doctor. Eighty four percent of the respondents would be willing to buy footwear prescribed to them by a doctor.

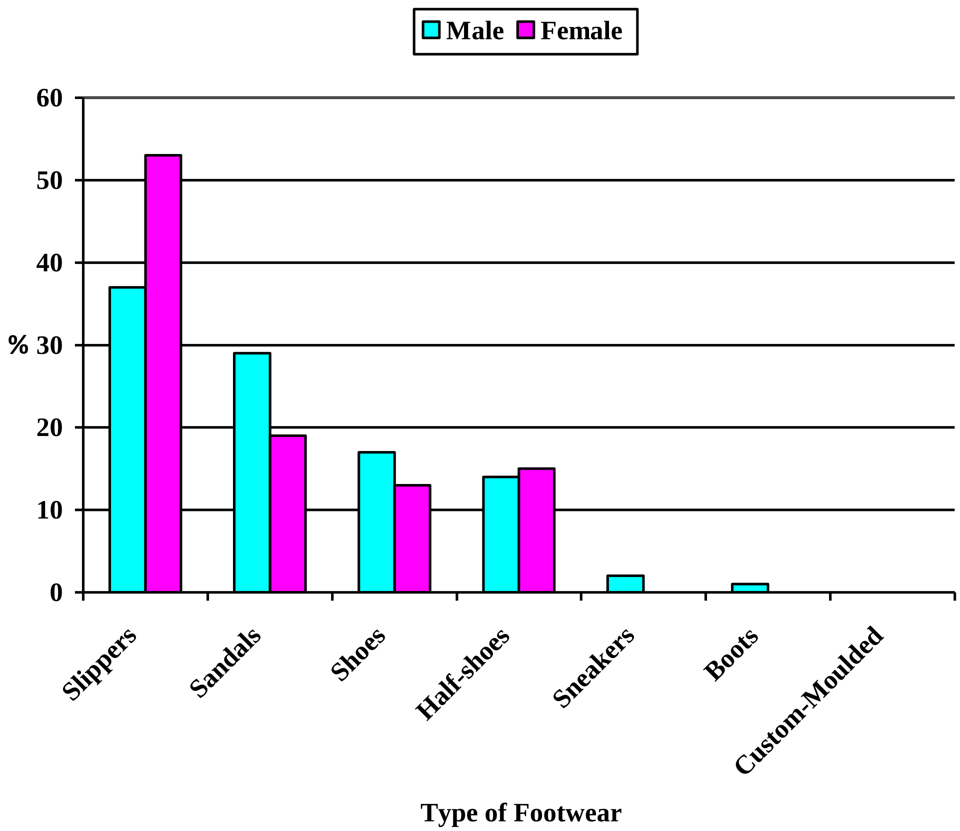


Fig. 3.10. Type of footwear most often used by participants.

Information gathered by the researcher through the questionnaire survey and presented in figure 3.10 has shown the top two footwear worn by the female respondents are slippers (53%) and sandals (19%). For the male participants, up to 37% wear slippers most often and 29% use sandals most times. None of the patients used custom-moulded footwear. Only 17% male and 13% female respondents wear shoes. This is seen as a very poor result because diabetic patients are expected to use footwear that gives good instep support.

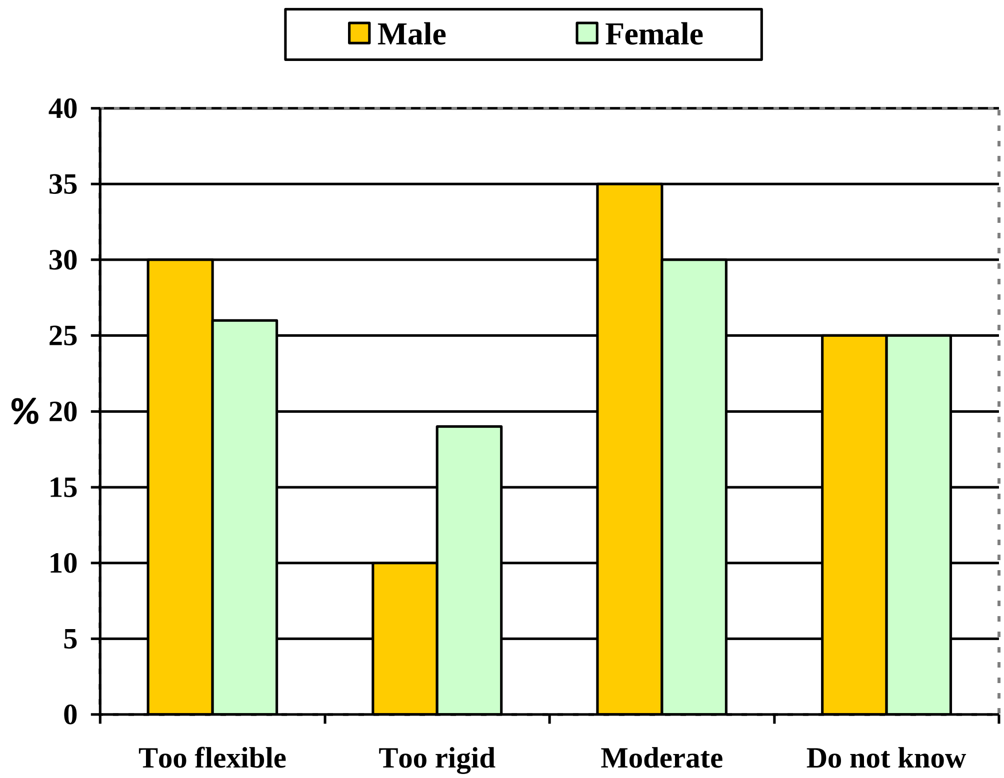


Fig. 3.11. Participants' view on the out-soles of their footwear.

In this study, the nature of the out-sole often used by diabetic patients was investigated. Figure 3.11 presented above indicates that 35% male and 30% female respondents' out-sole of their footwear were neither too rigid nor too flexible (i.e moderate). The percentages of patients wearing footwear with flexible soles were 30% (male) and 26% (female). A quarter of the participants could not describe the nature of the out-sole of the footwear. Nineteen percent of the male respondents indicated that the out-soles of their footwear were too rigid, but only 10% of the female patients reported that the out-sole of the footwear were too rigid.

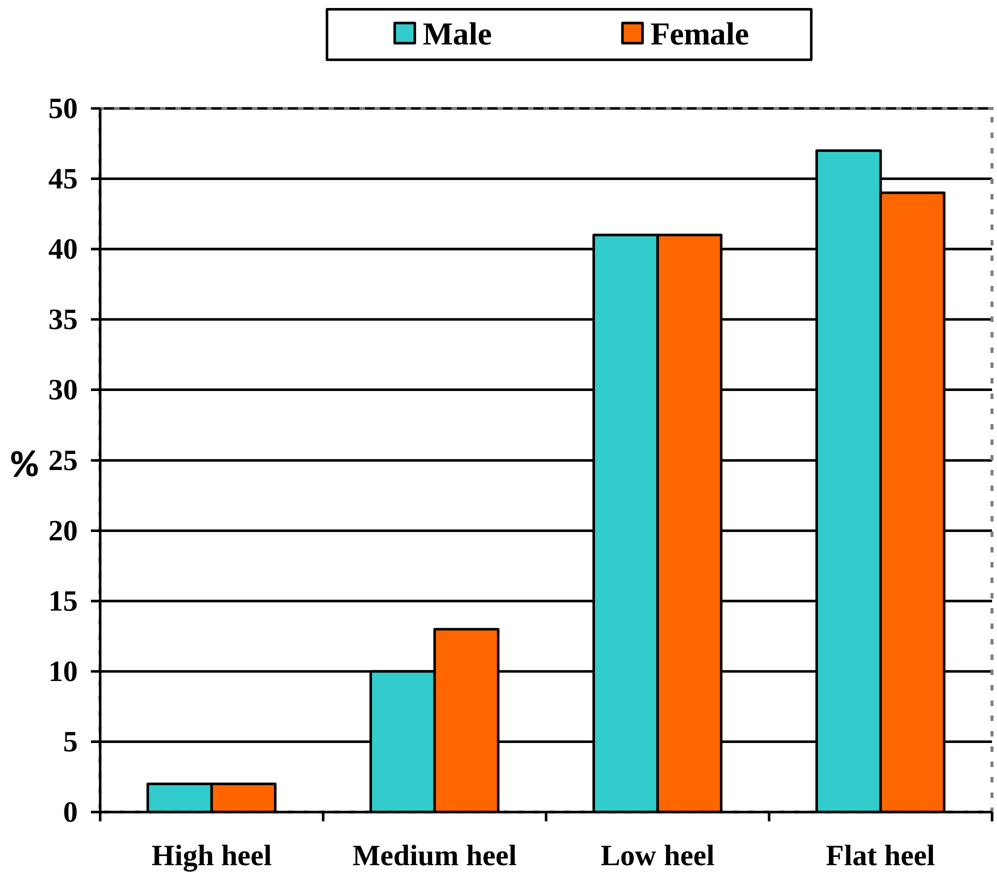


Fig. 3.12. Preferred heel construction.

Figure 3.12 clearly shows that the majority of the male patients preferred footwear that have low heel (41%) and flat heel (47%). Similarly, 44% and 41% female patients preferred footwear made with flat and low heels respectively. A significant percentage of the patients would prefer medium heel footwear. But a very low percentage (2%) of both male and female like wearing footwear that have high heel.

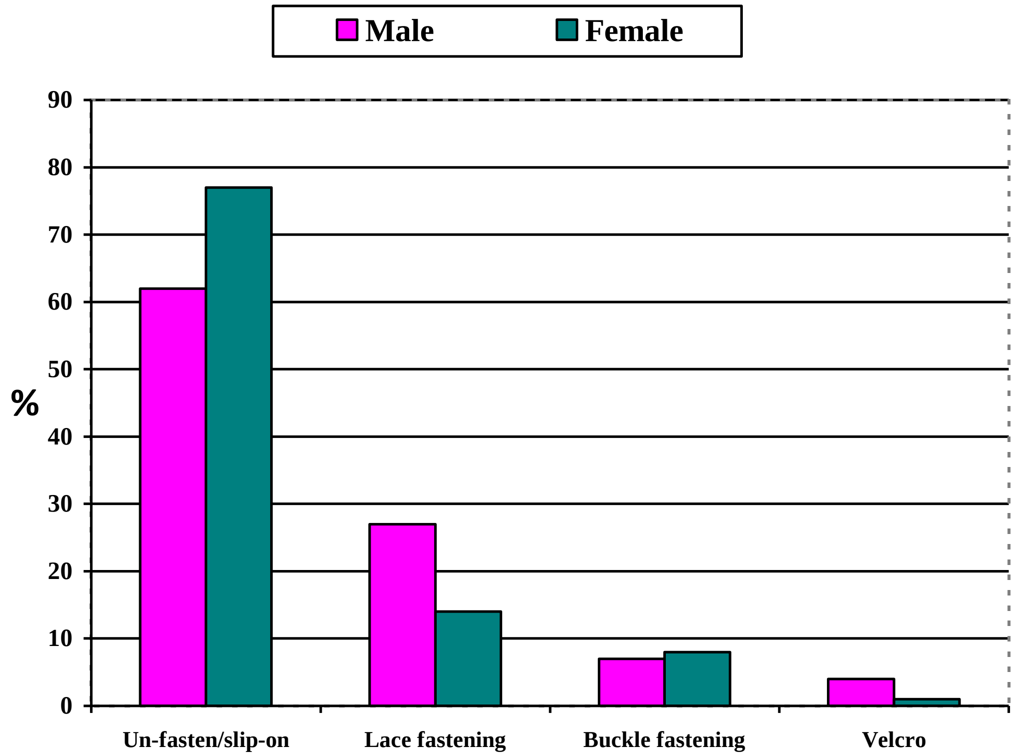


Fig. 3.13. Style of footwear used most often.

In regards to shoe fastening, figure 3.13 provides information on the preference for the different types of shoe fastenings or otherwise. The findings indicate that up to 77% females and 62% respondents used footwear that do not have any form of fastening or are slip-on footwear. Lace-up shoes were used by 28% of the male participants and only 12% of female patients used a similar type of footwear. Footwear with buckle and Velcro fastening were the least popular type of footwear used by the research subjects.

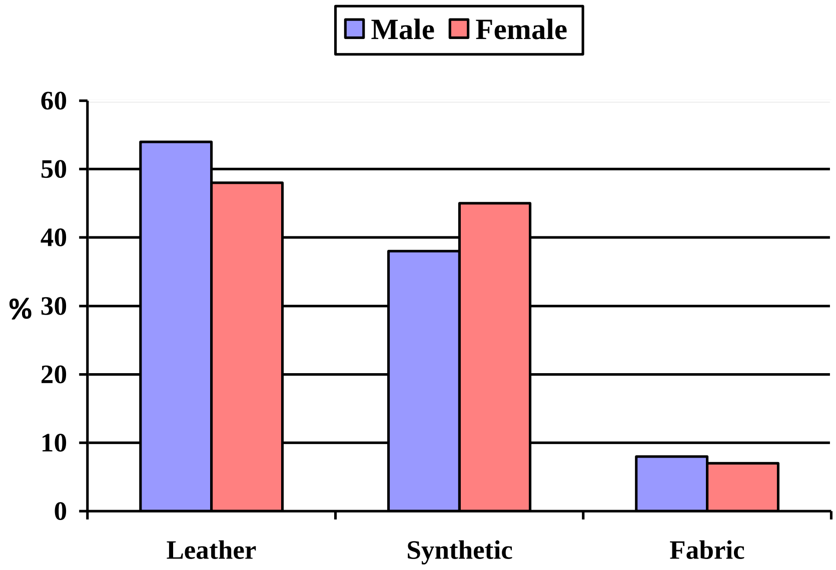


Fig.3.14. Preferred upper material.

Responded were asked to indicate their preferred shoe upper material and as shown in figure 3.14, more than half (54%) of the male respondents preferred leather and approximately half (48%) of the female subjects also preferred leather for their shoe upper. However, the percentage of the female participants that indicated that they preferred synthetic materials as shoe upper is also high (45%). Based on this survey, fabrics are the least preferred upper.

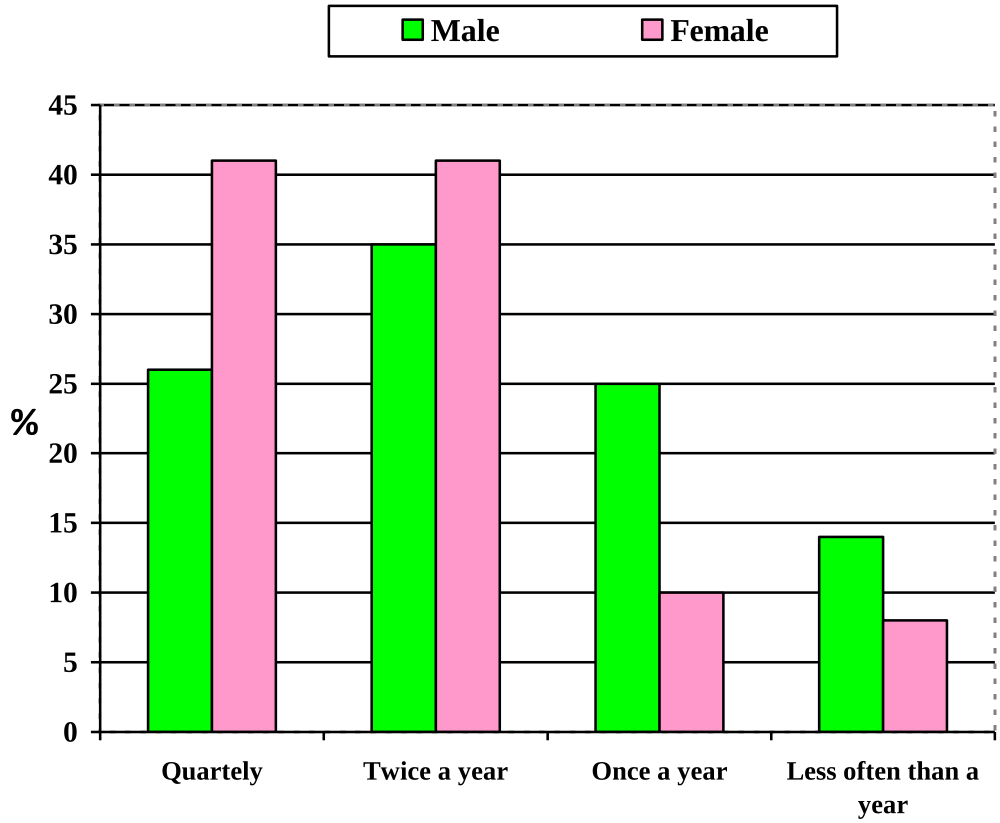


Fig. 3. 15 Frequency of purchasing footwear.

The frequency of purchasing footwear by the respondents is shown in figure 3.15. The frequency of buying shoes is highest among female subjects. 41% of the females indicated that they buy footwear quarterly, whereas 26% of the males reported that they buy footwear within that period of time. Looking at the chart above, male patients buy footwear less often than female patients.

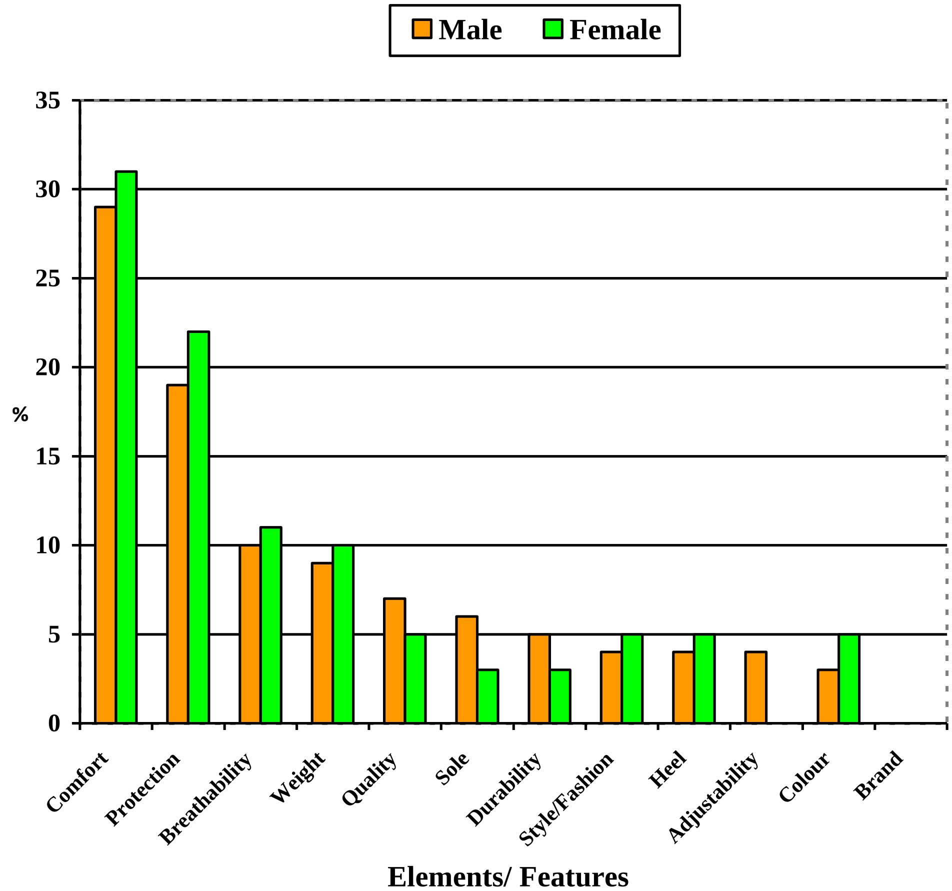
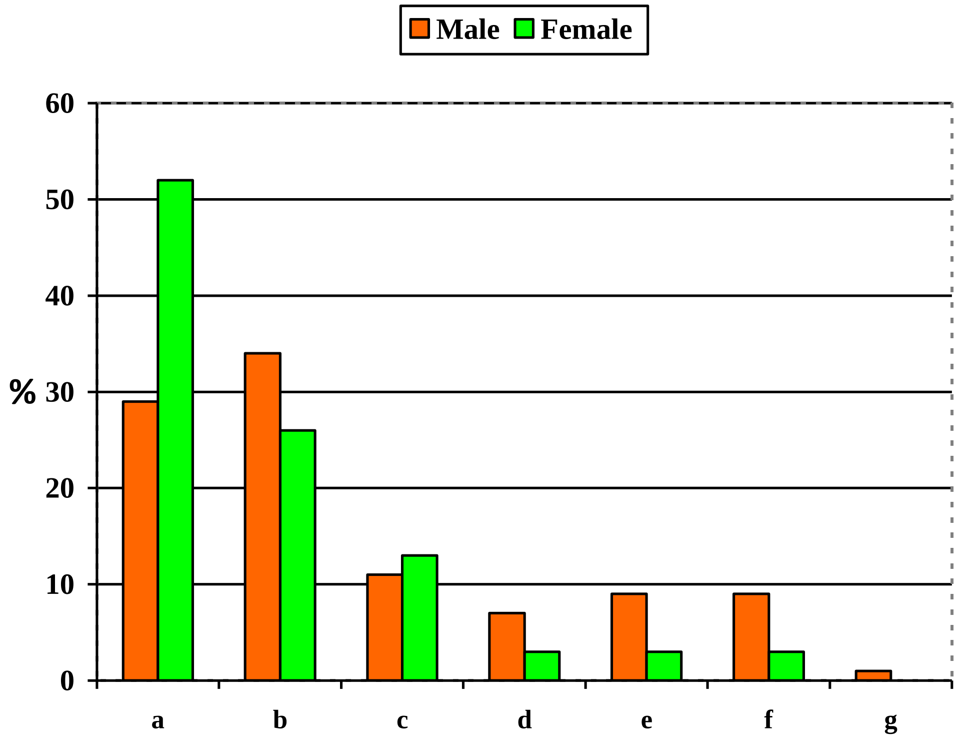


Fig. 3.16 Preferred footwear elements.

The questionnaire was partly designed to understand the elements respondents considered very important when purchasing shoes. The top four most preferred footwear elements from the result presented in figure 3.16 are comfort, protection, breathability and weight with values 28%, 18%, 10%, 8% and 31%, 22%, 11% & 10% for males and females respectively. Note that the outcome of this survey indicates that female patients (5%) give more preference to colour than male patients (3%). Whereas male took into account the adjustability of their footwear, female patients completely did not consider it as an important element when purchasing footwear. But both male and female reported that they were not bothered about the brand of the product (footwear) they buy.



(a) ₦100-1000 (£0.40-4.00) **(b)** ₦1100-2000 (£4.40-8.00) **(c)** ₦2100-3000 (£8.40-12.00)

(d) ₦3100-4000 (£12.40-16.00) **(e)** ₦4100-5000 (£16.40-20.00) **(f)** ₦5100-6000 (£20.40-24.00)

(g) ≥₦6100 (£24.00)

Fig. 3. 17. Amount willing to spend on a pair of footwear.

Figure 3.17 gives the outcome of the amount the patients were willing to spend on a pair of footwear. The result shows that the majority (52%) of the female respondents were not willing to spend more than ₦100-1000 (£0.40-4.00). Based on the data presented above, the tendency for diabetic patients in this part of the world to buy a pair of footwear that will cost up to ₦6100 (£24.00) and above is very low (1% for male & 0% for female).

3.6 Selected comments made by the participants.

Selected comments made by the research participants during the questionnaire survey are given below.

Diabetes foot problems and the role of footwear

The simple comment I have is that, at times one foot may be bigger than the other due to swollen, so something like elastic grip can be considered on slip on shoes.

Sometimes I walk barefooted without knowing because my shoes can go off my feet and I will not know.

I use slippers and even the slippers go off my feet without knowing that they have gone off my feet

If I am to trek from the hospital clinic to the gate, I have to rest 4 to 5 times before getting to the hospital gate and my slippers can go out from my feet without my knowledge.

My foot became too bad (rotten) due to diabetics, and so I cannot wear shoes, afterward I had to undergo amputation (on my left leg).

I am comfortable with wearing any type of shoe despite my condition.

The blisters due to diabetes is not yet severe to stop me from wearing my shoes.

My ulcered foot caused by diabetes has deprived me from wearing any type of shoes I like.

Diabetes have spoiled my legs (more to the left) and now I can't wear shoes

The condition resulted to the unhealing of my foot injuring I had rendered me unable to wear shoes.

My condition has made me scared of wearing shoes, less my feet get blistered and wounds.

I was using a half shoe with socks, which latter resulted to the injury on my left toe.

Prolong putting on of shoes with for 4 days made me have blisters, and subsequently complications. Now I cannot put on shoes.

Comfortable footwear should be made for diabetics. Diabetes patients should be given free treatment just like HIV and TB patients, because it is not all patients that can afford buying the drugs.

Initially, the little blister makes me uncomfortable, but now I can wear any type of shoe I want.

The pains I feel on my toes prevent me from wearing shoes comfortably.

The gangrene on my right big toe and the swollen condition of my right foot as a result of diabetes has prevented me from using shoes as I would.

Because of the wound on my left foot, I find it difficult to put on shoes.

Awareness

I have diabetics and I would like to be enlighten the more about the type of shoes to use. I received information from the clinic about the type of shoes I should use but I did not buy them.

I will be happy to wear any shoe so long as it will be good for my diabetic foot.

Preferred type of footwear

Comfortable footwear will be appreciated by me.

The footwear should be moderate and light.

3.7.0 Discussion

The findings presented in this chapter are discussed under the following sub-headings: subjects' gender and age, diabetics and foot problems, knowledge of foot care and footwear, footwear fitting/ features, footwear materials and components, preference for special footwear and cost.

3.7.1 Gender and Age

According to the results of the survey, the percentage of female participants (52%) was slightly more than that of the male (48%). However, Krentz and Bailey (2001) reported that the relative prevalence of diabetics among the sexes varies from population to population and no clear view has emerged.

Of the 156 studied diabetic patients, 50% were found to be in the age group 51-65 years and up to 31% were in the age bracket of 36-50 years. Those suffering with the disease that were 66 years and above accounted for 12% of the respondents. The mean age is 54.1 years old. The result obtained is at variance with the findings of Anselmo et al (2010) whose studies on the 'effectiveness of educational practice in diabetic foot: a view from Brazil' have shown a mean age of 62 years in the diabetic population in that country. Another research finding among diabetics in Nigeria reported a mean age of 54.6 years (Unachukwu 2007). These present findings are in complete agreement with the data published by Unachukwu (2007).

3.7.2 Diabetics and Foot Problems

Diabetics and diabetic foot disease with its related morbidity and mortality have become a serious global burden. Boulton et al. (2005) argue that most diabetic foot problems are preventable. And it has been pointed out (Wild et al 2004; Beran & Yudkin 2006) that the greatest rise in the prevalence of type 2 diabetes is likely to be in developing countries (particularly in Africa). Table 3.1 shows that 28% of the diabetic patients that participated in the survey have type 2 diabetes. The literature (see sub-section 2.4.0) also reported that the risk of developing diabetes differs according to ethnic group, Asian people and Black people being at higher risk of developing the disease than any other ethnic group in the world.

This survey has given a clear picture of the percentage of people suffering with diabetes and how long they have being living with the disease. It was discovered that just 27% (refer to fig.3.5) of the patients have being living with the disease for over 10 years. However, a similar survey (Tagang 2010) revealed that people in the developed societies (U. K) live with diabetes for longer period of time compared with people with the condition in the developing societies (looking at Nigeria as a case study).

In this study, it was discovered that up to 40% of the patients were suffering with foot problems like pains, ulcers, blisters, wounds, etc. Research has also shown that the prevalence rates of the disease in Africa are increasing and foot complications are rising parallel (Abbas & Archibald 2007). Another publication (Beran & Yudkin 2006) points out that type 1 diabetes in Africa is still uncommon but fatal, whereas type 2 diabetics is increasing in epidemic proportions.

Mansour and Dahyak (2008) state that “foot problems are common in patients with diabetes, often requiring prolonged and costly hospital stays and eventually leading to lower extremity amputation”. They found out from their study that 36.2% patients with diabetes in Basrah, Iraq had prominent foot abnormalities. In this study, it was discovered that the majority of the foot problems among the patients that participated in the study occurred at the toes (see fig.3.2-3.7). The result of this research is in agreement with a work published by Benn et al (2005) which reported that foot ulcers in diabetic subjects occur in the forefoot. With the understanding of the fact that forefoot pressure is higher than rear foot pressure, there is need for forefoot off-loading. Data from literature (U. S National Institutes of Health, 2011) also shows that almost 30% of people with diabetes aged 40 years or older have impaired sensation in the feet (that is, at least one area that lacks feeling).

3.7.3 Knowledge of Foot Care and Footwear

According to Boulton and Jude (2004), footwear is probably one of the major reasons for the lack of progress in reducing foot ulceration and amputation rates. In agreement with their assumption, up to 75% of the diabetic subjects that participated in this study reported that they have not received information about the type of footwear they should wear most often. Some comments (see sub-section 3.6) indicate that footwear cause and/ or complicate their foot problems.

An important finding of this study is the nature or type of footwear worn by diabetic patients in this part of the world. Our data give a very poor choice of footwear by people suffering with diabetes (see fig. 3.10). Poor knowledge of the diabetic foot complications, and lack of knowledge of the management of the disease are seen as the major reasons for the high percentage of diabetic patients experiencing foot complications in this part of the world. Therefore it has been advocated that patients' education on avoidable complications of diabetes and awareness of appropriate footwear for maintenance of good foot health should be emphasised by health care providers (Chandalia et al. 2008).

3.7.4 Footwear Fitting/ Features

Serious foot problems including foot ulceration can arise in the at-risk population due to ill-fitting footwear. Proper fitting footwear is therefore very important in the prevention of injuries. It has been pointed out that proper fitting footwear involves an understanding of feet, footwear and the correct selection of footwear to achieve a required fit (Goonetilleke 2003). It has also been suggested that footwear should be fitted only by practitioners trained in fitting footwear for diabetic foot (Wooldridge et al. 1998).

The data provided in this chapter (in table 3.4) shows that up to 29% of the subjects found it very difficult to put on shoes or to take off shoes and 31% agreed that their footwear needed modification in order to accommodate their feet well. The researcher argues that this percentage could have been higher if not for the fact that the majority of the subjects were wearing slippers as it had shown that most of the patients worn slippers (straps without back support) and sandals (see fig. 3.10 and appendix IX) and just 17% and 13% male and female subjects respectively worn shoes. On this issue of type of footwear worn by the patients, one of the subjects states that “I use slippers and even the slippers go off my feet without knowing that they have gone off my feet”. Generally, the majority of Nigerians wear open footwear. Appendix X provides photos of the most commonly used footwear in the country.

This finding points to the fact that a significant number of diabetic patients in Nigeria are wearing footwear that do not fit properly and lack the basic knowledge of proper fitting of footwear. They also do not have access to practitioners trained in fitting footwear for diabetic foot. It is believed that patients’ foot care education, particularly in regards to footwear, will significantly improve the poor choice of footwear by both male and female patients in this part of the world. Health care providers have a big role to play in this by making extra emphasis on good foot care practices and by giving patients information on avoidable complications and prevention. Whereas slippers and shoes are widely used in Nigeria and other countries like India (Chandalia, et al. 2008), shoes are found (Tagang 2010) to be the most widely worn type of footwear used in the UK and other Western countries.

One important consideration in footwear fitting for diabetic patients is in the choice of footwear style and shoe fasteners. Figure 3.10 clearly shows that majority of those that participated in the research worn improper footwear (i.e wrong styles of footwear and without shoe fasteners).

Footwear is much more that a material that covers the foot. It serves many roles like protection, comfort, fashion, performance in sport and improved foot health (Tyrrell & Carter 2009). In regards to some of these important elements, it was discovered from this study that diabetic patients ranked comfort, protection and breathability very high. Another element considered very important by the patients is the weight of the footwear.

Most of them preferred their footwear to be very light. This is a very positive outcome because in the prescription of therapeutic diabetic footwear, based on the International Diabetes Federation (IDF) Guidelines (Nather & Singh 2008), it states that: Footwear should be light, preferably less than 700g per pair and that the heel of the shoe should be under 5cm high to avoid weigh being thrown forward onto the metatarsal heads.

This shows that when designing shoes for diabetic foot, a range of factors that would improve comfort, protection, breathability and lightweight should be highly considered. Materials that cause discomfort should therefore be avoided or eliminated completely. Thorstensen (1993) explains that shoe comfort is related more to the take-up of liquid moisture and evaporation than to the passage of air or water vapour. He further explained that porosity and good air permeability do not necessarily imply comfort and good cooling of the foot. Information from the internet (http://hubpages.com/hub/walkfit-reviews) points out that most discomforts in the foot when shoes are worn are associated with improper cushioning in the shoes and it has been suggested that that desired cushioning can be provided by using extra inserts insole. Although cushion (extra inserts) insoles can give the patients an immense relief, certain precautions like wearing of loose shoes should be taken.

3.7.5 Footwear Materials and Components.

The analysis of the questionnaire indicated that both males and females preferred to wear shoes that are made with leather. This finding is in agreement with a research conducted in Singapore on “footwear habits in diabetics with and without foot problems” by Nather and other researchers (2008). But while the preference for fabric materials for shoe upper is very low (less than 10%), the female subjects that reported that they preferred synthetic materials are reasonably high (45%).

In this survey, the nature of the sole was another consideration. According to Dahmen et al. (2001), an out-sole designed for diabetic footwear can have different degrees of flexibility: stiff, toughened, or supple. A stiff outsole is necessary for the reduction of pressure in one particular area of the foot, correction of the foot shape, and immobilisation of the foot in the shoe. In addition, this inflexibility is needed to facilitate the distribution of forces exerted on the foot. But the outcome of this study indicates that 35% male and 30% female subjects wear footwear in which the out-soles were neither too flexible nor too rigid (i.e moderate out-sole).

The heel is another important component of diabetic footwear. It was found out that the majority (47% males and 44% female) of the participants preferred to wear shoes that do not have a heel or have a flat heel and up to 41% of the subjects preferred to wear shoes that have low heel. It is important to note here that very few (2%) people living with diabetes that participated in the survey like wearing high heel shoes. Research has shown that the heel of the diabetic shoe should be between 2cm and 3cm high and have a wide base to avoid instability. This will also help to avoid weight being thrown forward onto the metatarsal heads (Torreguiart 2009; Nather & Singh 2008; Meadows 2006).

3.7.6 Preference for Special Footwear.

Since compliance with wearing footwear designed for diabetic foot by people living with the condition is a major problem (Boulton & Jude 2004), the opinion of diabetic patients in regards to their willingness to use prescriptive footwear was sought. It was discovered that up to 84% subjects were willing to buy footwear that could cost double the amount they usually spend on footwear, if it is recommended by a doctor. Some reported that they would rather buy medicine for diabetes than buy footwear that would cost them double the amount they would normally spend on shoes. With comments like this, patient education on the role of footwear in the management and/ or prevention of foot problems must be seen as an urgent issue.

3.7.7 Cost

The cost of a footwear product is an important factor of consideration particularly for diabetic patients in underdeveloped countries. This study has revealed that only 9% of male and 3% of female subjects would be willing to spend up to six thousand naira or twenty four British pounds on a pair of footwear, while the majority (52%) of the female participants would not be able to spend more than one thousand naira or four pounds on a pair of footwear. 62% of the research participants in Nigeria would not be able to spend more than £20 on a pair of footwear (see fig. 3.17). When data presented in figure 3.17 are compared with the result in figure 3.16, it can be clearly seen that females buy shoes more frequently than men, but it was also observed that the male's patients buy more high quality and costly footwear than their female counterparts.

3.8 Chapter Summary

In summary, the key issues presented in this chapter are based on diabetic patients' viewpoint. The patients gave valuable information on a number of issues including their level of knowledge in regards to footwear, foot problems, foot care, footwear materials and components, etc. Generally, the patients' knowledge about diabetes and its complications, foot care, the use of appropriate footwear, etc was found to be very poor. In addition, the study also gives insight on the subjects' preferred shoe upper materials, heel height, footwear style/ features, etc. Inevitably, the amount the patients spent on footwear or would be willing to spend on prescriptive footwear was researched, because every manufacturer must take this into consideration. The next chapter investigates similar issues studied in this chapter but through structured interview survey with medical doctors.

Chapter 4: Data Collection with Interview Survey

4.1 Introduction

Many health care providers are aware of the damage footwear can cause to foot health particularly for diabetic patients, and how it could also be used as a therapeutic strategy in foot care. But unfortunately, many heath care practitioners who treat diabetic patients with foot problems or who are at risk of developing foot ulcers often ignored discussing footwear needs with their patients. Therefore, this chapter was partly designed to investigate health care practitioners' current knowledge and practice in regards to diabetic footwear. More so, the researcher interviewed medical doctors whose field of study and expertise differ from one another, but all of them have very good knowledge of diabetics and diabetic foot complications.

In this chapter, information on diabetics, foot-care services, diabetic foot problems, prescription of diabetic footwear, etc were gathered using structured interview method. The findings from the interviews are presented mainly in form of tables and charts and the results are discussed.

4.2.0 Aim and Objectives of this Chapter.

4.2.1 Aim

To explore the current state of medical knowledge and practice concerning the provision of foot care including provision of appropriate footwear for diabetic patients in Nigeria and the role of footwear in diabetic foot problems.

4.2.2 Objectives

- To investigate medical knowledge and practice concerning the provision of foot care.

- To understand the role of footwear in the management of diabetic foot-related problems from the viewpoint of medical doctors.
- Use the findings to develop diabetic footwear design framework.
- To identify areas that will require further study.

4.3 Protocol for Interview survey.

The protocol used to gather the required data from the interviewees is show as a flow chart in figure 4.1.

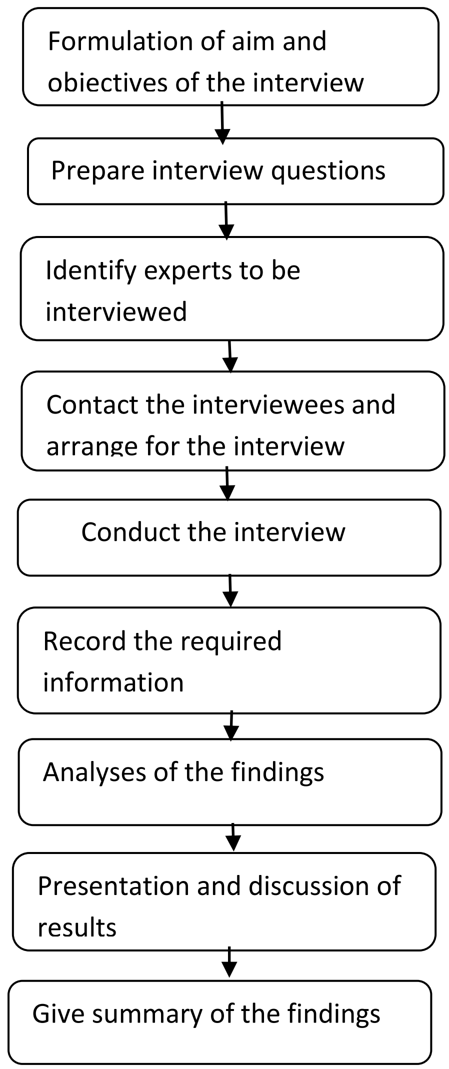


Fig. 4.1 Protocol for Interview Survey.

4.4. Method

Interview was solely used to gather the data presented in this chapter. It has been shown that Interviewing has a wide variety of forms, so the choice of interview technique will depend in large part on the aims of the study. The common type of interviewing is individual, face-to-face verbal interview, mailed or self-administered questionnaires, and telephone interview (Denzin 1998). In general, interviews may be divided into three categories; structured, semi-structured, unstructured interviews (Dawson 2009). For this method of interview, each respondent is asked a series of questions based on pre-prepared questions and fixed interviewing schedule where the same questions are posed to all respondents (Brace 2008; Gray, 2004). Structured interview was used to conduct this present study. The data generated through this structured interview are mainly quantitative. However, in order to gain in-depth understanding on some complex questions to be asked, some open-ended questions were asked that generated qualitative data. This approach was used by the researcher because it allows a wide range of information to be collected from the research respondents. Furthermore, structured interview is seen as an efficient method of conducting an interview because it limits the researcher's subjectivity and bias, it is efficient with regards to time, it allows the researcher to control the topic and format of the interview and make it easier for the researcher to code, compare and analyse data (Holloway and Wheeler 2010).

For a successful interview, Doody and Noonan (2013) advocate that researchers should develop their technique, choose the right method and carefully prepare for all aspects of the process. In this research, a pilot survey was initially planned and conducted. Six doctors from three government hospitals were interviewed to validate the questionnaire. The pilot survey provided the researcher with valuable information that was used to plan and conduct the main survey successfully. During the actual survey, forty-five medical doctors were interviewed and their mean years of experience as medical practitioners was found to be 10. 2. The researcher discussed his proposed sampling size with his supervisors before the actual commencement of the study. It was agreed that a sampling size of 30-50 medical doctors would give a good outcome. The data was collated using spreadsheet, following which the data was processed and analysed with Excel 2010.

4.5 Ethical considerations and Standard Operating Procedure.

Ethical approval for this study was obtained from the appropriate institutions namely: (1) De Montfort University, Leicester; (2) Ministry of Health, Kaduna State; and (3) Ahmadu Bello University Teaching Hospital, Zaria, Nigeria (look at appendices XI (a), XI (b) & XI (c)). During the interview, each participant at the beginning of the study was given information on the aim of the study, the nature of the survey and the general format of the interview. The participants were also informed of the anonymity and confidentiality of their personal data and their right to withdraw from the study at any time. Hence, the interviewees entered into the research voluntarily and with adequate information. No one was subtly coerced or unduly influenced to participate in the research. Therefore, the identities and institutions of affiliation of the respondents were kept anonymous.

A Standard Operating Procedure (SOP) was designed for the study. It consisted of structured questions that helped the researchers in the planning and selection of the interview questions, identification of research participants and location. The SOP (see appendix VII) was also used to guide the researchers in the step by step conducting of the survey.

4.6 Findings

The response from each medical practitioner was encoded and analysed. The data gathered from the interviews are presented in this chapter mainly in form of tables and charts. The following section provides the outcome of the expert interview.

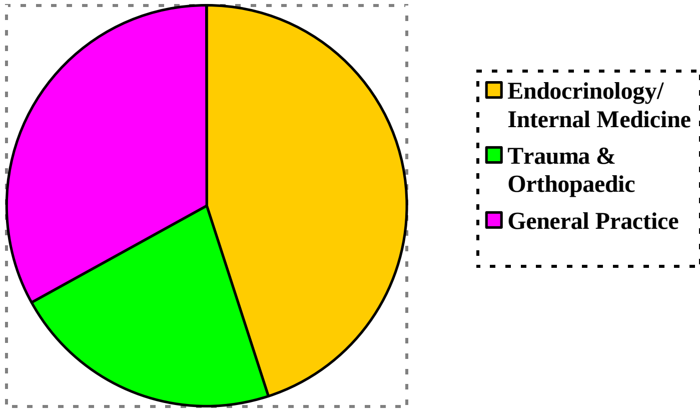


Fig. 4.2. Doctors' Areas of Specialization.

Forty-five medical doctors that participated in the study were asked to indicate their area of specialization/ medical specialty. Figure 1 shows that 45% of the doctors were endocrinologists, 22% orthopaedic specialists and 33% participants were general practitioners.

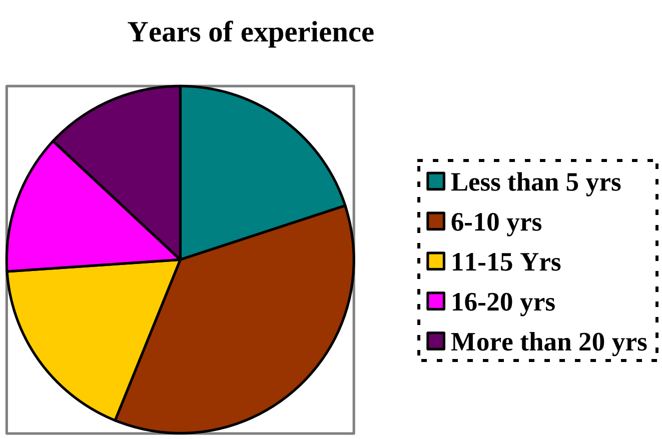


Fig. 4.3 Doctors' Years of Experience.

Figure 4.3 shows that the doctors that participated in the survey had varying years of experience with 36% having 6-10 years of experience. The second highest group (20%) is those with 5 years or less experience in medical practice. The findings have also shown that 18% of the respondents fall in the category of those that have 11-15 years of experience. Those with 16 – 20 years were 13% and those with over twenty years of experience in medical practice were also 13% of those that participated in the study. From this result, it shows that almost half (44%) of the doctors interviewed had over ten years of experience as medical practitioners. The mean years of experience of the respondents is 10.2 years.

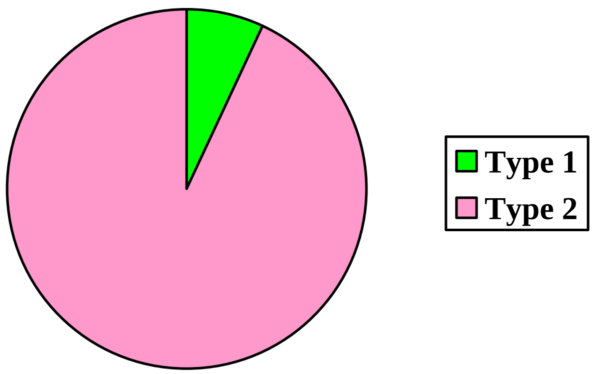


Fig. 4.4 Type of diabetics treats mostly.

Figure 3 gives information about the type of diabetes the respondents treat the most. The findings of this study indicate that up to 93% of diabetic patients in Nigeria could be suffering with type 2 diabetes and less than 10 (7%) could be suffering with type 1 diabetes.

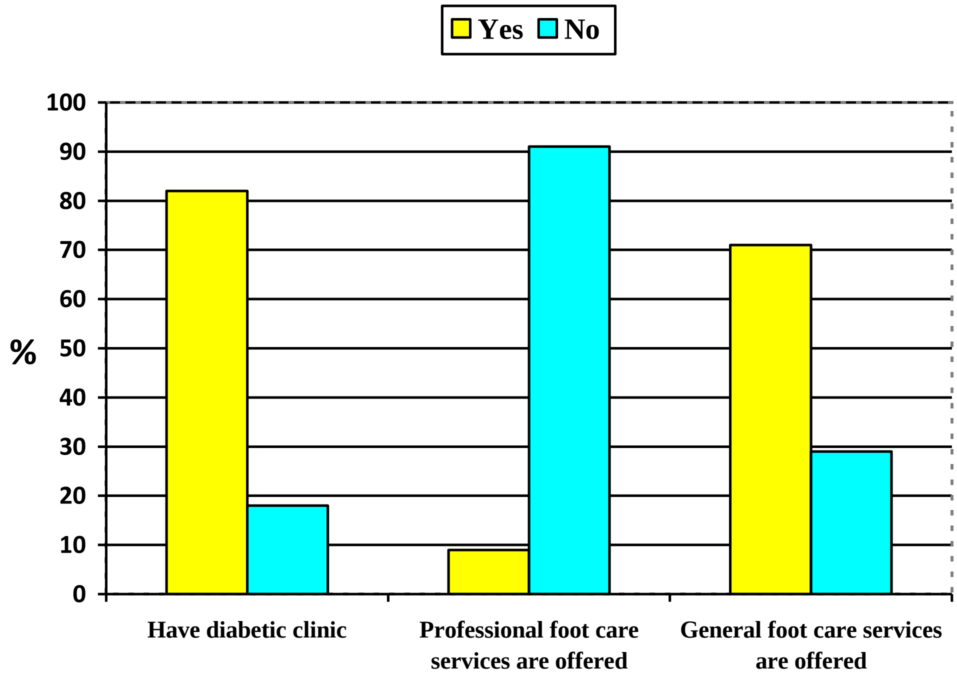


Fig. 4.5 Availability of foot care services.

The result of this research presented in figure 4.5 shows that up to 80% of the doctors interviewed work in hospitals that have a diabetic clinic. However, almost all (91%) the respondents point out that there are no professional foot care services available for diabetic patients in Nigeria. But up to 71% of the doctors believe that foot care services are rendered to people suffering with diabetes.

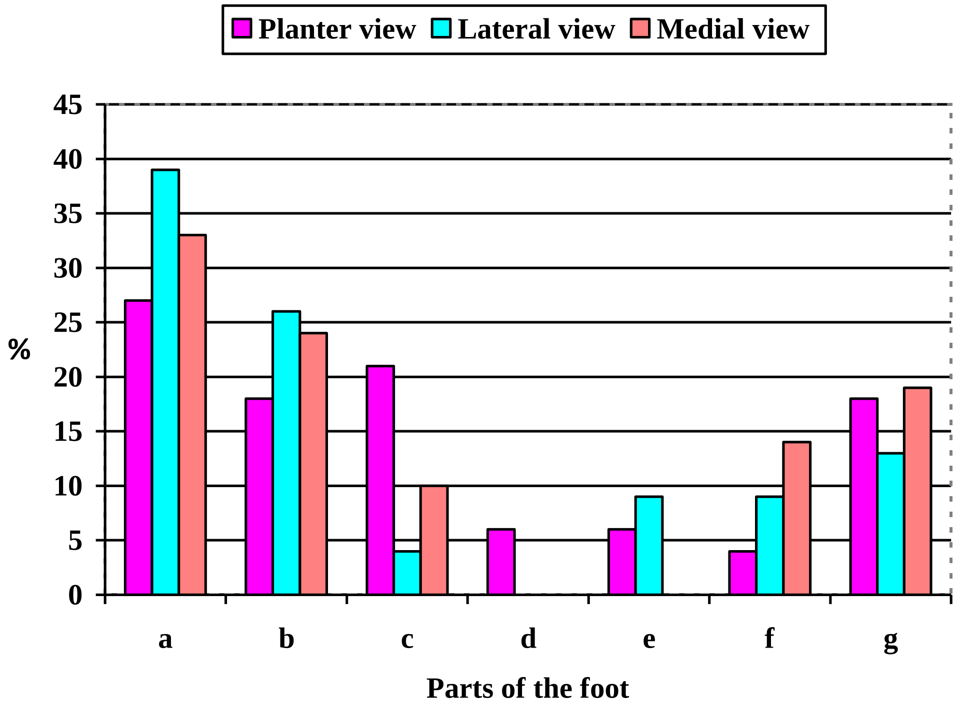
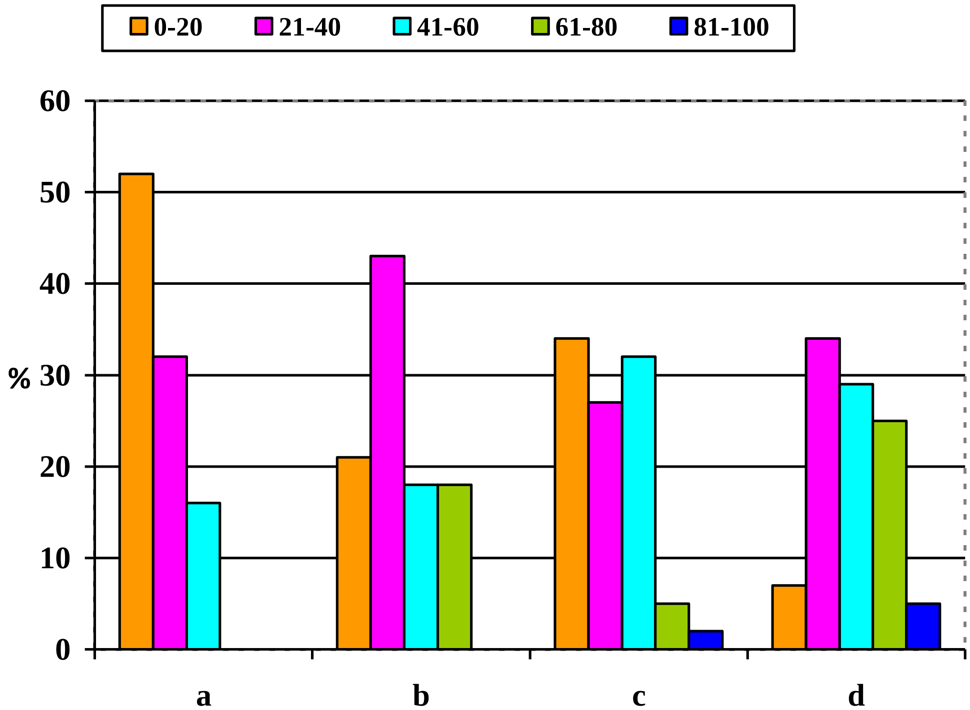


Fig. 4.6 Score on parts of diabetic foot mostly ulcerated (refer to fig. 3.3, 3.5, & 3.7)

Three different views (see appendix V) of the human foot were presented to the respondents to indicate the particular parts of the diabetic foot that is mostly ulcerated. The results shown in figure 4.6 clearly point out that the toes are mostly likely to become ulcerated with values up to 39%. Based on their experience, the doctors indicate that the heel is second top location that ulcers mostly occur.



a - Diabetic patients that received foot amputations.
b - Percentage of diabetic patients that cannot use regular footwear.
c - Diabetic patients with foot problems.
d - Diabetic patients that complaint or report of pains/ numbness to their feet.

Fig.4.7 Diabetic patients with foot problems.

Figure 4.7 gives four important findings from the survey. The first item shows that up to 20% of diabetic patients could experience amputation during their life time according to the views of over half (52%) of the respondents and 32% of the doctors believe that diabetic patients that receive amputation could be put in the range of 21-40%. The second item gives an insight into the percentage of people suffering with diabetes that may not be able to wear regular footwear. It is clearly shown that up to 40% of patients suffering with diabetes may not be able to wear regular footwear based on the opinion of 43% of the doctors interviewed. The third item provides information about diabetic patients with foot problems. Based on the findings, 34% of respondents indicate that up to 20% of the diabetic population could be suffering with foot problems and 27% think that up to 40%

of diabetic patients may have foot problems. However 32% of the doctors gave a higher range (41-60%) of their clients that could be suffering with foot problems. The fourth item clearly indicates that 34% of the respondents believe that diabetic patients that complaint of one form of foot problem or the other could be up to 40%.

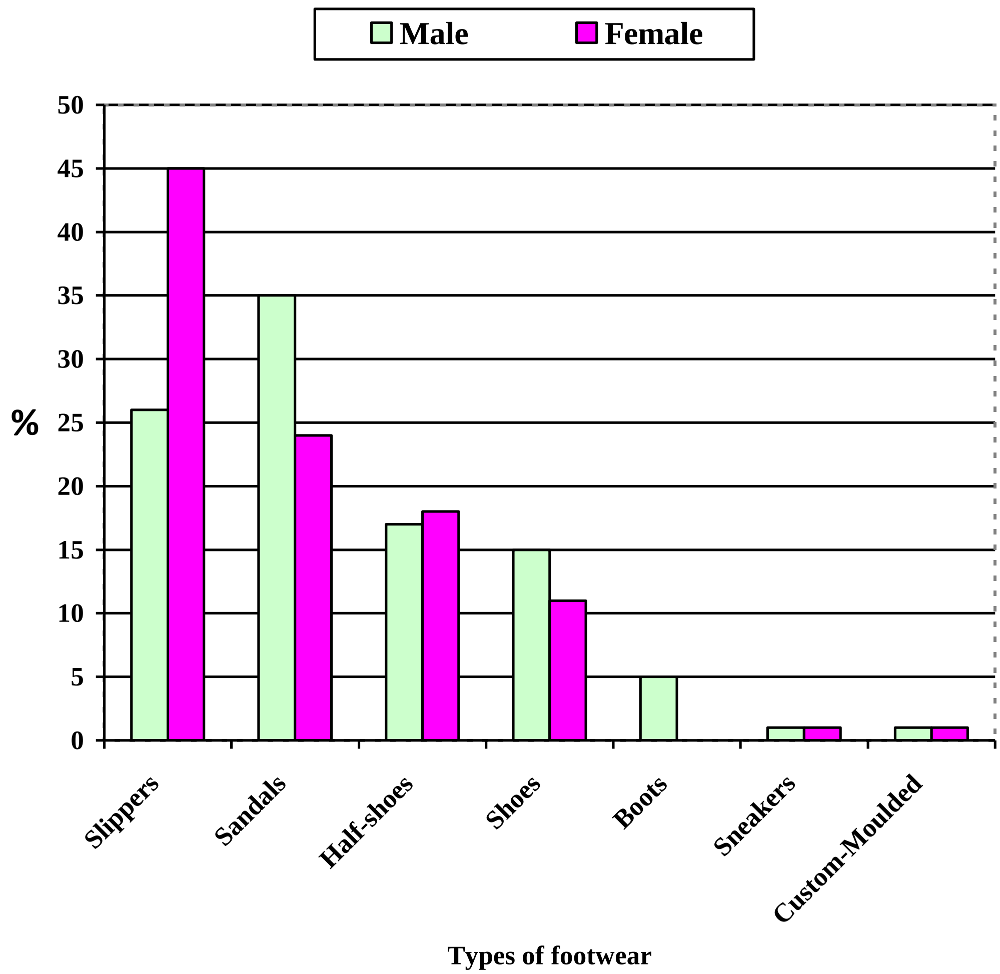


Fig. 4.8 Type of footwear often used by the diabetic patients.

Based on the rating of the doctors on the type of footwear their clients use most often presented in figure 4.8, up to 45% females' patients wore slippers to their clinic and up to 26% males used slippers. On the other hand, sandals are the favourite (35%) type of footwear used by the males' patients whereas 24% female patients wore sandals. It can be observed from the result in figure 4.8 that the lowest ranked type of footwear worn by the patients were sneakers and custom-made or medical footwear. The percentage of patients that used shoes are 15% and 11% for male and female respectively.

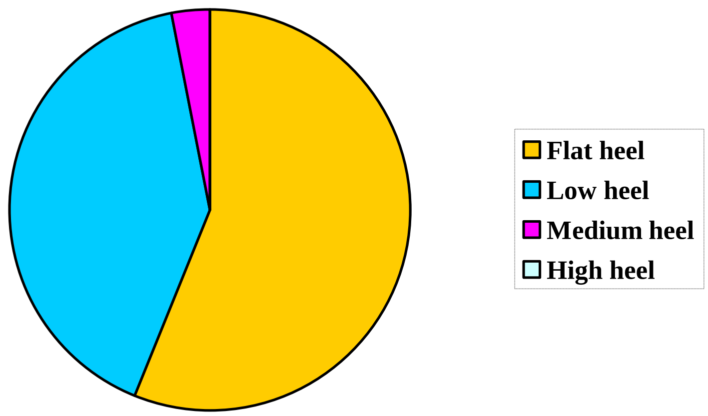


Fig. 4.9 Preferred heel construction for diabetic footwear.

From the view points of the doctors interviewed, presented in figure 4.9, a large percentage (56%) would prefer their clients to wear footwear with flat heel. The doctors ranked footwear with a low heel as the second most preferred type of heel construction for diabetic footwear (41%). Interestingly, none of the respondents think that high heel footwear should be used by their clients and only 3% advocate for medium heel footwear for diabetic patients.

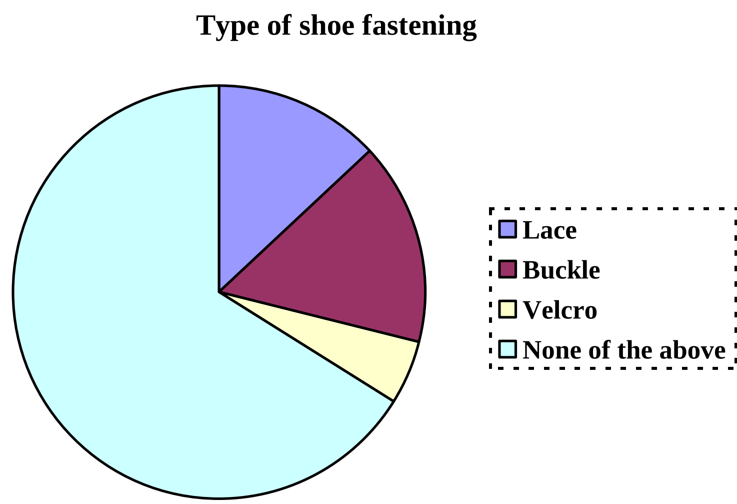


Fig. 4.10 Type of shoe fastening.

The result on the type of shoe fastening used most often by diabetic patients shows that 34% wear shoes that have one form of fastening or another. On the other hand, up to 66% of people suffering with diabetes may be wearing footwear that do not have any form of fastening, i.e. mainly slip on footwear.

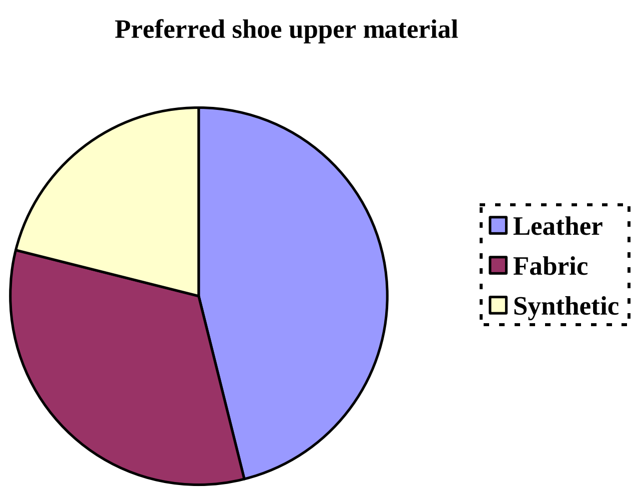


Fig. 4.11 Preferred upper material.

From the view point of the doctors that participated in the study, on the preferred type of shoe upper material for making diabetic footwear as presented in figure 4.11, leather (with 46% preference) stands out as the most preferred shoe upper material. Fabric and synthetic materials have 33% and 21% preference respectively.

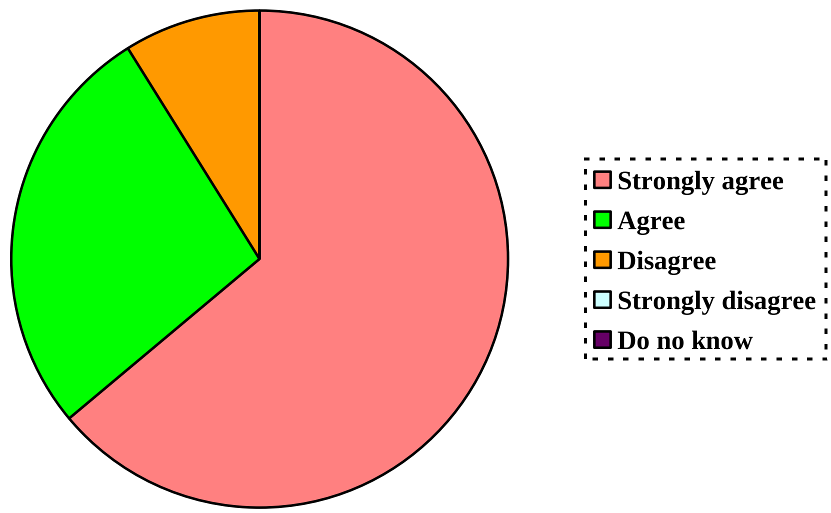
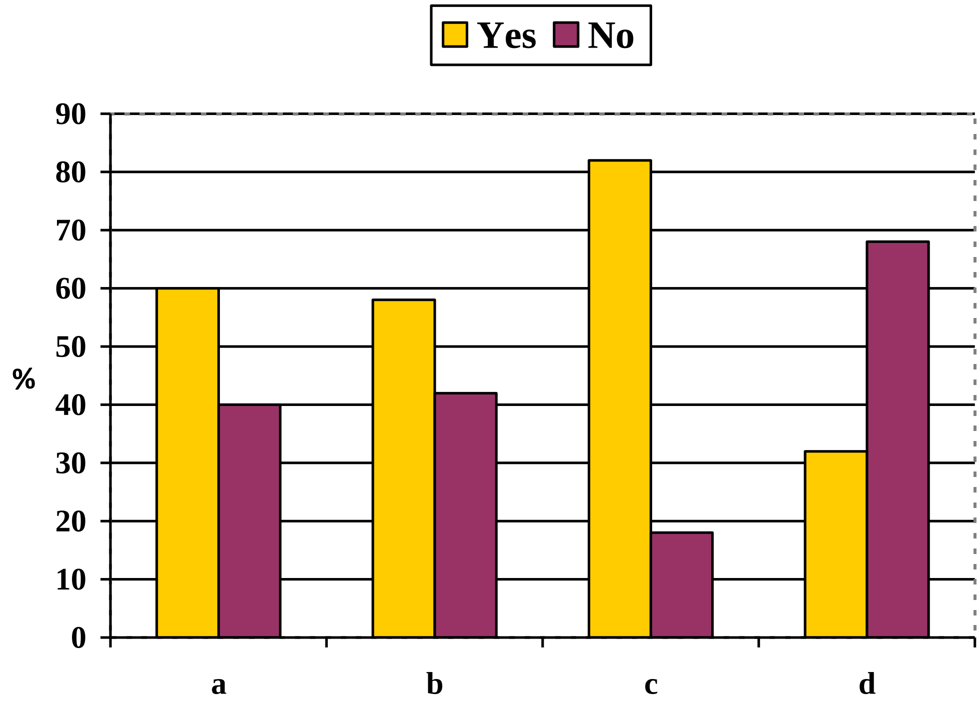


Fig. 4.12 Foot ulcer related to pressure from too narrow footwear.

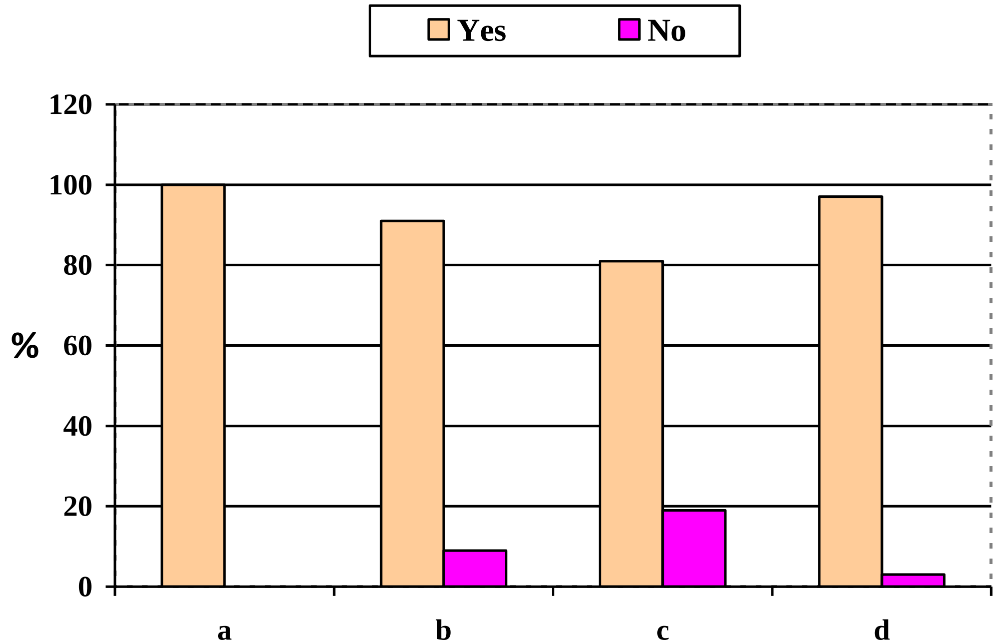
Figure 4.12 gives the findings about the possibility of foot ulcers being related to wearing of inappropriate footwear. The pie chart clearly shows that up to 91% of the respondents agreed that ulcers could be related to wearing of inappropriate footwear. However, 9% of the doctors interviewed do not think that ‘bad’ footwear could lead to foot ulcers.



a. Have your patients ever reported any bad footwear experiences (e.g pains, blisters, etc)?
b. Are there often diabetic foot problems relating to a particular aspect or part of footwear?
c. Do you think ill-fitting footwear could be one of the major problems that lead to foot amputations?
d. Are regular shoes able to accommodate the foot of diabetic patients?

Fig. 4.13 Foot problems in relation to footwear.

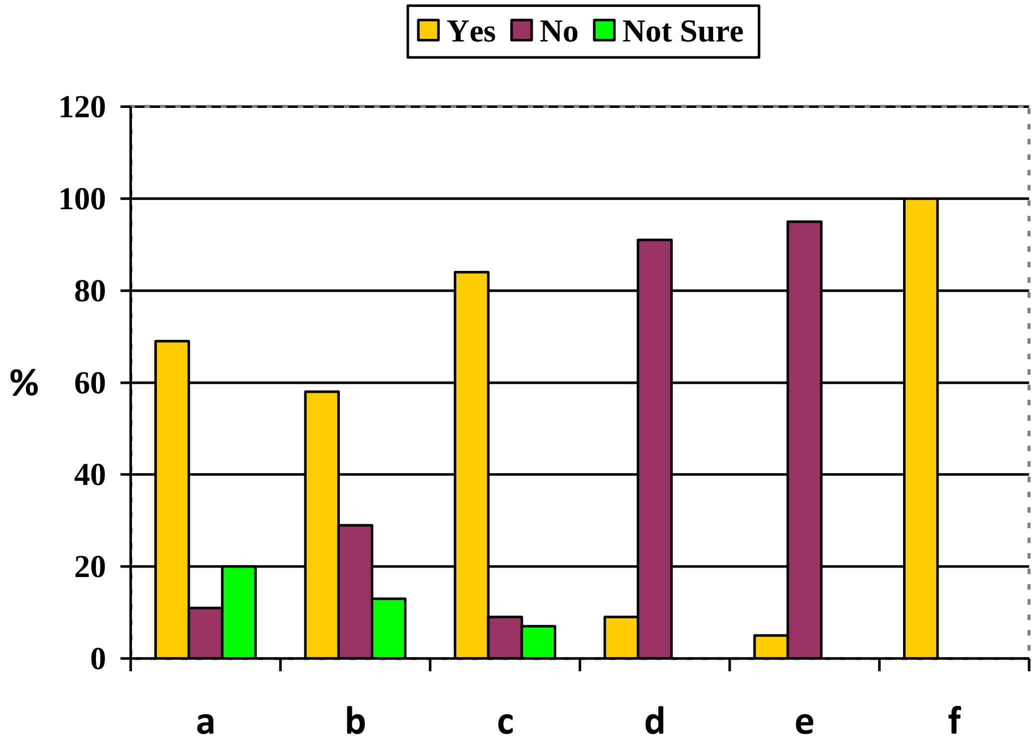
The findings of the study given in figure 4.13 show that the majority (60%) of the doctors interviewed had encountered patients that reported bad footwear experiences like blisters, ulcers etc at one time or the other. A very high percentage (82%) of the respondents believe that poor footwear could contribute to a major foot problem that may lead to amputation. The outcome of the survey also indicates that 68% of the medical specialists interviewed had encountered diabetic patients with foot problems that caused regular shoes to be unable to accommodate their feet.



a. Do you think 'good' footwear can protect the feet of your diabetic patients from injury?
b. Risk of foot amputation may double for diabetic patients who do not obtain prescribed (specially designed) footwear.
c. Do you think your diabetic patients are happy to use special footwear (e.g orthopaedic)?
d. Do you think footwear should be regarded as an important consideration in the clinical management of many foot disorders or problems?

Fig.4.14 The role of footwear in the management of diabetic foot problems.

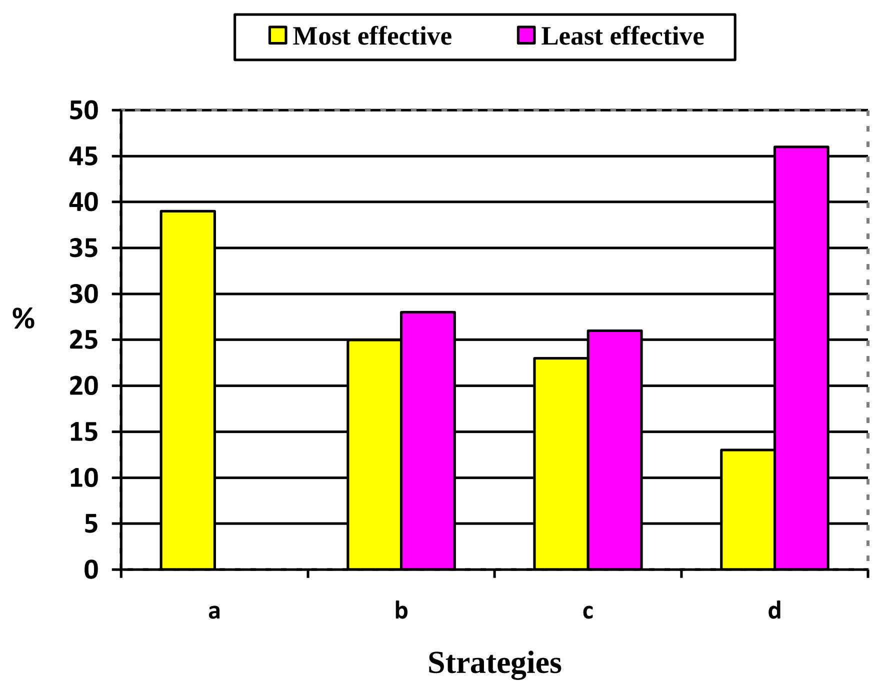
The findings provided in figure 4.14 indicate all the doctors that participated in the study believe that 'good' footwear would protect the feet of their clients from injury. The study further revealed that foot amputation may double for diabetes patients who do not obtain prescribed footwear and only 29% of those interviewed knew of orthopaedic footwear makers in Nigeria. One of the most interesting findings about this survey is the view of the doctors with regards to consideration of footwear for the clinical management of foot problems. Nearly all (97%) the respondents believe that footwear should be regarded as an important consideration in the management of foot disorders or foot problems.



a. Prescriptive footwear cannot be sourced locally.
b. No footwear makers or technicians with knowledge of footwear modification in Nigeria who can make shoes to the requirements of your patients' foot problems.
c. Footwear available in Nigeria markets is not meeting foot care requirements of diabetic patients.
d. Are you aware of any foot care programmes for diabetic patients in Nigeria?
e. Are you aware of any footwear programmes for diabetic patients in Nigeria?
f. Do you think that medical specialists or clinicians have need for further education about prescription of orthopaedic/ therapeutic footwear to patients with foot problems?

Fig. 4.15 Level of awareness/ education about prescription footwear.

Based on the outcome of the study, 69% of the respondents point out that prescriptive footwear cannot be sourced locally and 20% were not sure if specially designed shoes for diabetic foot could be sourced locally or not. But 11% indicated that prescriptive footwear could be sourced locally. In regard to knowledge of footwear makers that could make shoes to the requirements of diabetic patients in Nigeria, more than half (58%) of those interviewed believe that there are no shoe makers in the country that could provide specially designed footwear for diabetic patients. But 29% of the doctors believe that there are footwear technicians in the country that could make footwear to the requirements of diabetic foot problems. Nearly all (84%) the doctors interviewed state that footwear available in Nigeria markets are not meeting foot care requirement of diabetic patients. Of the 45 doctors that participated in the study, 91%, 95% and 87% point out that there is not a foot care programme, no footwear programme and no professional foot care like podiatric services in Nigeria respectively. The study further revealed that foot amputation may double for diabetes patients who do not obtain prescribed footwear. All the doctors that participated in the survey advocate that medical specialists or clinicians that consult diabetic patients should be given an opportunity to be educated about prescription footwear.



a. Improving glycemic control
b. Self management and education
c. Use of appropriate footwear
d. Improving blood pressure and lipid control

Fig. 4.16 Strategies for prevention of diabetic foot problems.

To gain insight into the strategies to be adopted for prevention of diabetic foot problems, the opinions of the respondents were sought. The figure above (fig.4.16) indicates that the use of appropriate footwear with a score of 23% for most effective strategy has great potential to reduce the incidence of diabetic foot problems.

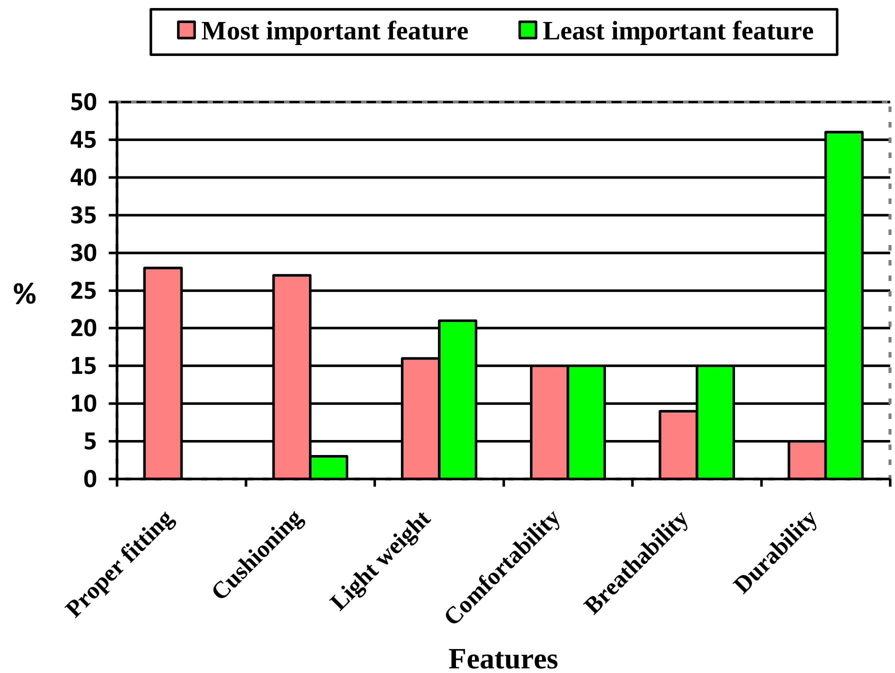


Fig. 4.17 Preferred diabetic footwear features.

When footwear is designed for diabetic foot, the features outlined in figure 4.17 should be critically considered. According to the views presented here, the top three features to emphasize are proper fitting, cushioning and light weight. However, less emphasis cannot be paid to other features like breathability of the upper materials and this must be taken into account when designing footwear for people suffering with diabetes.

4.7 Selected comments by respondents on different aspects of the study.

Some important comments made by the experts interviewed are outlined below. The doctors' comments were based on their experience with diabetic patients (refer to appendix V)

1. Diabetic foot problems in relation to footwear

- *Tight fitting footwear and non customized wears that are ill-fitting when feet are deformed.*
- *Numbness, ulcers and callus formation due to too tight shoes/ ill-fitting shoes.*
- *Blisters around the 1st metatarso-phalageal joint (bunion) which later progress.*
- *Pressure ulcers from shoes that are too tight.*
- *Too tight, flexible for sharp object to penetrate, too loose for it to get off unaware.*
- *Blisters on the toes due to tight footwear.*
- *Pain at the heel and presence of corns on the big toes and last 2 digits.*
- *Not properly covered footwear, sometimes no footwear at all.*
- *Footwear with tight distal ends.*
- *Toes, especially the big toe, then the dorsum of the foot.*
- *The heel and the forefoot.*
- *Patients with diabetes who use slippers- slip on can easily sustain injuries especially when they have peripheral neuropathy.*
- *Footwear with covered front and those whose buckles about directly over the malcoh.*
- *Nail piecing shoes, shoes removing from patients' foot without their knowledge.*
- *Choice of wrong footwear due to lack of knowledge.*
- *Dorsum of the foot around the toes, heels and other pressure areas.*
- *Pointed part of shoes and hard soles; medial and lateral aspect of the foot are most readily affected by tight and hard footwear.*
- *The dorsum of the foot and the lateral sides.*

- *Secondary infected ulcers are the most common cause of amputation in diabetic patients; good glycemic control is the best method of controlling and preventing amputation, even with good footwear.*

2. The experience of amputees in regards to footwear before their operation

- *Most of them are not careful about the type of footwear they use.*
- *Some of them experienced pain, heaviness and eventually numbness leading to blister formation, ulceration and gangrene.*
- *Some reported unwanted problems like unhealing foot injury and more frequent numbness.*
- *Poor knowledge of footwear.*
- *Would have loved to have the shoes prescribed but not within reach.*
- *Most of them have never been educated about care of the foot before their operation.*
- *Most of them are not regular on medications, follow up and also foot care*
- *Footwear are useful.*
- *Footwear services not available.*
- *Tight and hard footwear and long immobility periods.*

3. Attitudes of patients towards the use of prescribed footwear

- *They want to wear shoes that resemble shoes worn by the populace.*
- *Somehow stigmatizing around those who know.*
- *Expenses of customized shoe.*

4. Need for Patients' education or enlightenment on use of diabetic footwear

- *Organizing workshops/ seminars to creating awareness and recommendation for the use of diabetic footwear.*

- *Health education on footwear for clients who are diabetic is very important. Programmes of enlightment is also relevant especially in the rural areas.*

5. Need for training and further education for professionals dealing with diabetic patients.

- *There is definitely need for medical specialists to pay more attention to their diabetic patients footwear as part of the general care for the patients. Care of the foot should be taken very seriously. There's also need to train more technicians who will be skilled in the fitting and manufacturing of the special light diabetic shoes.*
- *Diabetic foot ulcers/ sepsis is the common non-traumatic cause of amputation of human limbs worldwide and Nigeria has a great burden of diabetes mellitus. There is paucity of multidisciplinary approach to diabetes with orthopaedics being the least consulted until very late in the management. Thus there is need for early referral to orthopaedics and the need for orthopaedic surgeon to rise to the challenge to prevent this depressive event and not just to amputate a limb.*
- *Please more of this information and education of footwear should be introduced in health care facilities and to health workers.*

6. Communicating the outcome of the study.

- *Report to footwear industries on outcome of your research*
- *This research shall be a pacesetter in the area of diabetic footwear in Northern Nigeria (even in Nigeria as a whole) as diabetic ulceration/ sepsis is a leading cause of non-traumatic foot amputation and prevalence of Type II DM is on the increase due to increase in the incidence of non-communicatable disease in the country especially metabolic syndrome.*
- *Please kindly communicate your findings to the various hospitals where your survey was carried out so as to improve our knowledge and share knowledge, thank you.*

- *Please when you are through with this research, I beseech you to come back to Nigeria and give your recommendations to the Federal Government. Thank you, It's a lovely research topic.*

4.8.0 Discussion

The interview survey has given an insight into a wide range of issues about diabetes and diabetic footwear. The findings of the survey are grouped and discussed under four main sub-headings. First, the nature of diabetic foot problems, second, footwear worn by diabetic patients in this part of the world, third, the role of footwear in the prevention/ management of diabetic foot problems and last but not the least, prescription of appropriate footwear for diabetic patients.

4.8.1 Method and Respondents.

In this study, structured interview questions were used to collect information on the research areas from forty-five medical doctors with varying years of experience. The mean years of experience of the respondents was found to be 10.2. The interview provided insight into medical opinions about the issues discussed below. Although this approach allows a wide range of data to be collected, further work on larger groups of medical practitioners from all relevant specialties (nurses, medical doctors, etc) and from all the regions of the country may enable more characteristics of diabetic patients' footwear needs and solutions to be identified.

In addition, further studies evaluating the impact of footwear practices on the diabetic foot such as foot ulcers and amputations using a similar or different approach would further help to determine the potential for interventions to improve practice and reduce complications.

4.8.2 Diabetics and foot problems

It has been pointed out that there are two major types of diabetes namely: type 1 and type 2. This study reinforces the fact that large percentages of people with diabetes are suffering with type 2 diabetes. Previous publications have clearly shown that type 1 diabetes affects 10-15% of people with diabetes and type 2 affects 85-90% of people with the disease (Nazarko 2011; WHO 2006; McIntosh 2006). It is well known that people with diabetes experience foot ulcers, swollen feet and different types of foot deformations. The literature (Bakker 2011; White 2010) indicates that 50% to 80% of all amputations are diabetes related and ulcers precede the majority of these amputations.

Diabetic foot problems are one of the most widespread and upsetting preventable complications of diabetes. Up to 32% of the respondents believe that diabetic patients that have foot problems in this part of the world may be up to 60%. Similarly, a large proportion (68%) of the doctors indicated that regular shoes are unable to accommodate the feet of their patients due to one type of foot problem or another. With regards to patients that reported a bad footwear experience like blisters and ulcers, the result shown in figure 4.13 indicates that foot problems could be related to wearing ill-fitting footwear. Other authors (Dargis et al. 1999; Frykberg et al. 2006; Diabetes UK 2009) argue that inappropriate footwear is probably the reason for high foot ulceration and amputation among diabetics, and that wearing appropriate shoes could potentially avert many foot problems.

In this study, 82% of the specialists interviewed think that inappropriate footwear could be one of the major causes of foot complications that could lead to foot amputations. This is in line with previous studies (Bakker 2011; Unachukwu 2006) that indicated up to 80% of all amputations are diabetes related and ulcers precede the majority of these amputations. The medical experts further pointed out that many clinicians have over-looked the importance of footwear in the management of diabetic patients and they believe that this work will create more awareness among health care providers and patients on the use of appropriate footwear in the management of diabetic foot problems. Another study carried out by Caselli (2011) to determine the causes of lower extremity amputations identified that for nearly half of the amputees, the initial event that lead to the amputation was either shoe-related or may have been averted by wearing appropriate shoes. Likewise, in this study it was discovered that 91% of the doctors interviewed (see fig. 4.14) believe that the risk of foot amputation may double for diabetic patients who do not obtain prescribed footwear.

According to the respondents, majority (82%) of diabetic foot problems could be related or linked to wearing of ill fitting or in appropriate footwear that contributes significantly to the susceptibility of the diabetic foot to injury and infection. This scenario is not different from what has been reported from other centers in Sub-Saharan Africa and other less developed countries (Unachukwu 2006; Abass & Archibald 2007; Chandalia et al 2008) where foot complications from inappropriate footwear continue to exact a very high cost on society as a result of the associated disability, morbidity and mortality. To change this dreadful situation, Jeffcoate et al (2008) advocate that therapeutic interventions in the prevention of diabetic foot complications should be sought and promoted and that this that would result in cost effectiveness for both healthcare providers and the patient. Another group of researchers (Mayfied, et al. 2000) suggest that identification of a foot problem by clinicians should be followed by appropriate treatments including prescription of appropriate footwear in order to prevent serious complications.

4.8.3 Footwear worn.

In this study, patterns of footwear were generally similar for both men and women except for more frequent use of open toe footwear (slippers) by women. In addition, up to 66% of people suffering with diabetes may be wearing footwear that does not have any form of fastening. It was also observed that the type of footwear considered most appropriate for diabetic patients to use (For example custom molded, sneakers, shoes etc) were the least frequently worn. This finding is similar to an earlier study which revealed that provision of professional diabetic foot care services and the use of protective diabetic footwear were sub-optimal in both developing and developed countries. Rubbing from footwear was identified as the definite cause of 35.0% of foot ulcers reviewed as part of a prospective study conducted in the United Kingdom. Furthermore, the follow-up of 472 patients at The Royal Prince Alfred Hospital Diabetes Centre (NSW, Australia) identified that 54.0% of all foot ulcers that developed in this group, could be directly attributed to trauma from footwear (Bergin 2013; Ferguson 2012; Abbas & Archibald 2007).

The consistent use of appropriate footwear is important in all diabetic patients, especially those who demonstrate loss of protective sensation from peripheral neuropathy. This patient group, who are unable to feel pressure and/or pain caused by inappropriate or ill-fitting shoes are more likely to develop blisters, callus and corns. These early complications require prompt intervention if ulceration and potential amputation are to be avoided. The simple measure of wearing appropriately fitted or prescribed footwear has been shown to significantly reduce plantar foot pressures, therefore decreasing the likelihood of developing callus and ultimately ulceration (Bergin 2013). Custom-made footwear (e.g orthopaedic shoes) is seen as appropriate footwear that could be prescribed to a wide variety of patients to diminish or prevent foot problems (Netten et al. 2010). Unfortunately, in this study it was discovered that custom-made footwear is not being prescribed to sufferers of diabetics in the country, even those with foot problems.

These findings brought out a very poor choice of footwear made by both male and female diabetic patients in Nigeria. The frequent use of slippers and inappropriate footwear has serious consequences like susceptibility of the patients' feet to injury and infection. This situation requires a joint effort on the part of the health care providers and the footwear industry. However, to reduce foot problems, patients must be willing to receive education about foot care in order to improve their choice and selection of footwear.

4.8.4 The role of footwear in the prevention of diabetic foot complications.

It was discovered from this study that provision of appropriate footwear has not been given prominent in diabetic foot care in Nigeria. To accommodate changes in foot structure, diabetic footwear is designed to redistribute and reduce pressures underneath the foot and avoid mechanical stress on the dorsum of the foot. This can involve the fabrication of accommodative insoles that follow the contours of the plantar foot surface (total contact) but it can also involve the use of fully customized (therapeutic or orthopedic) shoes, which often also incorporate corrective elements such as arch supports, metatarsal pads and bars, or specific outsole configurations. Fully customized footwear is predominantly prescribed to diabetic patients with a prior foot ulcer with the goal to prevent recurrence of ulceration (Frykberg et al. 2006; Ferguson 2012 & Rizzo et al. 2012; Bus et al. 2013).

The author therefore support recommendations that all patients with diabetics should be offered foot care education aimed at improving footwear related knowledge and practice to reduce the risk of foot complications (Abbas & Archibald 2007). More so, several studies suggest that most diabetics and especially those with previous foot ulcers do not uniformly adhere to these recommendations and select their footwear from a variety of styles, shapes and colors for different activities. Dissatisfaction with prescribed footwear is thought to stem from improper fit, unacceptable appearance, high cost, excessive time between ordering and receiving prescribed shoes, limited colors, styles, materials and durability (Ferguson 2012). There should be extra emphasis on patient education on diabetes and awareness of avoidable complications and their prevention by following good footwear practices. Individuals with diabetes need consistent and ongoing education from health care providers regarding the role and importance of the regular use of footwear and the type most appropriate to their level of risk of ulceration (Bergins et al. 2013; De Berardis et al. 2005). This study therefore, reinforces the need for improve footwear practices for those who have diabetes.

4.8.5 Prescription of appropriate footwear for diabetic patients.

The level score of knowledge of medical doctors in this part of the world on foot care and provision of special footwear like orthopaedic/ diabetic footwear is very low (see fig. 4.15). The findings are in complete agreement with a previous study (Frykberg 2006) that revealed lack of knowledge of foot care among patients and health care providers in Africa and other less developed countries, leading to further foot complications. Therefore, diabetic patients with foot problems or at high risk of developing foot ulcers actually need swift intervention including provision of appropriate footwear to avoid amputation.

This study revealed that:

- There is a lack of awareness of foot care issues among patients and health care providers alike
- Very few professionals have an interest in the diabetic foot or are trained to provide specialist treatment
- Podiatry services are not common in Nigeria
- Training programs for health care professionals on diabetic foot management are non-existent

To help patients make informed choices about self-care, particularly in relation to footwear, the author believes that provision of relevant knowledge, education, and information will go a long way in improving their foot health. With respect to the need for education about prescription footwear among the respondents, all the research participants indicated that they would be happy to be educated about prescription of orthopaedic or appropriate footwear.

In this study 81% of the participants reported that their diabetic patients would be happy to use orthopedic footwear if prescribed by their physician. The majority also agreed that footwear programs for patients with diabetes in their practice were not adequate. It has been pointed out that every person with diabetes is at risk of foot ulceration and that this is often taken to mean that every diabetic person should receive ongoing podiatry care (McGill, et al 2005; Krentz & Bailey 2001). But in this study, it was discovered that podiatric services have not been made available to patients in Nigeria. Therefore, there is an urgent need to train medical or paramedical professionals in the area of diabetic foot care to tackle the challenge of diabetic foot problems.

Through market survey and in the light of the views presented in this chapter, it can be argued that footwear available in the Nigerian market is not meeting foot health requirements of diabetic patients. To solve this problem, the author suggests that government and non-governmental organizations should sponsor a research project to design and develop new sustainable product concepts, such as footwear and insoles for diabetic feet in the country.

From the study, it is understood that the incidence of diabetic foot problems can be dramatically reduced through appropriate management and prevention programmes. Frykberg et al. (2006) also point out that foot care programmes emphasizing preventative management can reduce the incidence of foot ulceration.

Figure 4.5 points out a lack of specialist clinics for diabetic foot care, for example screening services for foot ulcers. This finding is in agreement with previous study that revealed that there is still lack of awareness of foot care among patients and health care providers in Africa and other less developed countries, leading to further foot complications (Abba & Archibald 2007).

4.8.6 Diabetic Footwear Design Features.

The researcher understood from the various experts interviewed certain elements or features to be considered critically in order to design or make good and acceptable footwear for people living with diabetes. It was discovered that majority (66%) of the patients may be wearing footwear that do not have any form of fastening. That is, most of them are using slip-on or slippers with no fasting mechanism most often. It is really regrettable to observe that footwear with important fastening features like lace, buckle or velcro are the least likely type of footwear to be used by diabetic patients in Nigeria (see fig. 4.10). A respondent comment that "too loose footwear sometimes get off patients' feet unaware" (see 4.8 (1)). This comment demonstrates the importance of wearing footwear with a fastening. In addition, Chandalia et al. (2008) and Shiu & Wong (2011) argue that use of inappropriate footwear like slippers without back strap predisposes patients to foot injury. When commenting on footwear fundamentals, Huard (n. d) states that the key parts of footwear that can significantly affect the wearer's safety and comfort include the toe and metatarsal areas.

A large percentage (56%) of the respondents think that footwear design and constructed for diabetic feet should be made with flat heel, whereas up to 41% would like their patients to wear low heel footwear (see fig. 4.9). These views are at variance with a previous publication that indicates that medium to low heel should be used in the design and construction of diabetes footwear (Nathan & Singh 2008).

This study also provides data on the most preferred upper materials for diabetic footwear construction. Leather stands out (with 46% preference) as the most preferred shoe upper material. However, other materials like fabric are seen as good materials for diabetic footwear construction based on the doctors' views.

Generally, wide footwear is recommended for diabetic patients, particularly those that have a deformed foot. Tight fitting and hard footwear must be avoided because they can cause pressure ulcers. Also, flexible footwear that sharp objects can easily penetrate must be avoided.

4.8.7 Service Delivery.

In some developed countries, the approach to foot care is exemplary and provides a model to inspire, especially in low resource settings. It has been shown that it is possible to reduce amputation rates by between 49% and 85% through a care strategy that combines: prevention; the multi-disciplinary approach in the use of appropriate footwear; close monitoring, and the education of people with diabetes and healthcare professionals. Healthcare decision-makers also have a key role to play in removing the barriers to implementation that still exist in many countries. However, in most countries, including developed countries, foot care is not yet at the level of funding, organization and professionalization that would facilitate the ready attainment of these objectives. Given that the goals are both possible and affordable in many contexts, it is possible to learn from those foot-care settings where standards are being set (Diabetes UK 2009b; Rouleau et al. 2010 & Chen 2011).

4.9 Chapter Summary.

The researcher successfully gathered relevant information on diabetic foot problems and the role of footwear in the management of diabetic foot problems from medical practitioners who see diabetic patients. The particular aspects of the present study that was addressed through the interview survey are: diabetes/ diabetes foot problems, the role of footwear in the management of diabetes foot problems, appropriate footwear for people living with diabetes and the cost of diabetes footwear. The views presented in this chapter have shown that prescription of protective or orthopaedic footwear has the potential to reduce the incidence of footwear-related ulcers and amputations.

It was also discovered from this study that the use of appropriate footwear in the prevention of diabetic foot complications is sub-optimal. It is therefore important that healthcare professionals support and stimulate research in establishing a diabetic footwear programme in the country.

To help patients make informed choices of self-care, particularly in relation to footwear, health care providers should always give diabetic patients relevant information and assistance on how to recognize footwear broadly suitable to the maintenance or improvement of foot health and the type of footwear that should be avoided as being potentially detrimental. The author believes that the views presented in this chapter are an accurate portrayal of the current role of appropriate footwear in the management of diabetic foot amongst clinicians in Nigeria. The findings also provide areas for future research that could potentially increase awareness among health care providers in Nigeria treating diabetic patients, particularly those with foot problems or at-risk of developing foot complications. The next chapter provides information on experimental analysis of shoe upper materials.

Chapter 5: Experimental Analysis of Footwear Materials.

5.1 Introduction

In previous chapters (3 & 4), the views and beliefs of medical doctors and diabetic patients on key features that could be considered for designing comfortable footwear were explored. In this chapter, a short study on footwear materials was undertaken on the basis that clinicians and manufacturers/ retailers have since agreed that the materials used to manufacture footwear are very important in regards to foot health (Venon 2007). However, there are wide ranges of materials that can be used in footwear manufacture such as leather, synthetic, fabric, etc. and each of these materials has its own specific properties. They differ not only in their appearance, but also in their service life, physical properties and treatment required. Some of these materials are exceptional in the way in which they offer practical solutions to problems of foot comfort. But the choice of one material over another for shoe making is determined by functionality, availability, and comfort (Thornstensen 1993). Although currently there is a widespread replacement of leather with synthetics (man-made materials) as solings in almost all types of footwear, leather is still considered by far the most widely used upper material. Therefore, in this research, some important comfort and performance properties of this same material (leather) based on the findings of the questionnaire and interview surveys (refer to chapter 3 & 4) were determined.

Footwear upper materials are described as the materials forming the outer face of the footwear that cover the upper dorsal surface of the foot and attach to the sole assembly (British Standard, 2005). And as already known, leather is a generic term referring to a material made from hide or skin of a vertebrate through tanning processes which renders it non-putrescible under warm, moist conditions (Covington 2009; Kite & Thompson 2007; Rose 1992).

Moreover, it has been stressed that leather is the most used natural material for footwear making because it presents ideal characteristics for footwear (Bata 2013). Leather is soft, breathable, offers very good absorption ability and is able to adjust to an individual's foot shape. Leather is seen as a versatile material for footwear design because of its breathability and insulating properties. Other materials like coated fabrics and poromerics are excellent in regards to water repellency and resistance, but because foot comfort depends on absorption of foot perspiration and its transmission through the upper, some of these materials are not satisfactory. Research has also shown that foot comfort properties of coated fabrics and poromerics are poorer than leather (Harvey 1992). Therefore, to demonstrate that the selected shoe upper leathers that would be used to make the trial prototypes (refer to chapter 7) would meet the required standards, experimental analysis of some important parameters like water vapour permeability and tensile strength are critical. The laboratory analyses carried out on the selected shoe upper materials include; thickness measurement, water vapour permeability, tensile strength etc.

Physical properties give a glimpse into the potential advantages of any given material. Therefore, the material analysis was an attempt to investigate the physical properties of shoe upper leathers for their suitability for diabetic footwear manufacture or otherwise. These properties can be extrapolated or determined by subjecting the different materials to a number of tests such as tensile strength, water vapour permeability, etc (World Footwear 2013). But most research on designing footwear for people has concentrated on comparing different shoes or materials rather than comparing the basic physical characteristics of the materials that are used (Goonetillete 2003). Therefore, in this chapter basic physical and foot-comfort properties of shoe upper materials were determined.

5.2.0 Aim and Objectives of this chapter.

5.2.1 Aim

To investigate appropriate footwear upper materials through analysis of key physical parameters that determine performance of shoe upper material and foot comfort.

5.2.2 Objectives

- To investigate appropriate shoe upper materials for making diabetic footwear.
- To study the physical and performance properties of shoe upper leathers.
- To determine the suitability of different types of leather for diabetic footwear design/ manufacture.
- To give recommendations on suitable shoe upper materials for making diabetic footwear.
- To identify areas that would require further investigations.

5.3 Protocol for Analysis of Shoe Upper Materials.

The protocol used to carry out the experimental analyses is provided below (fig.5.1).

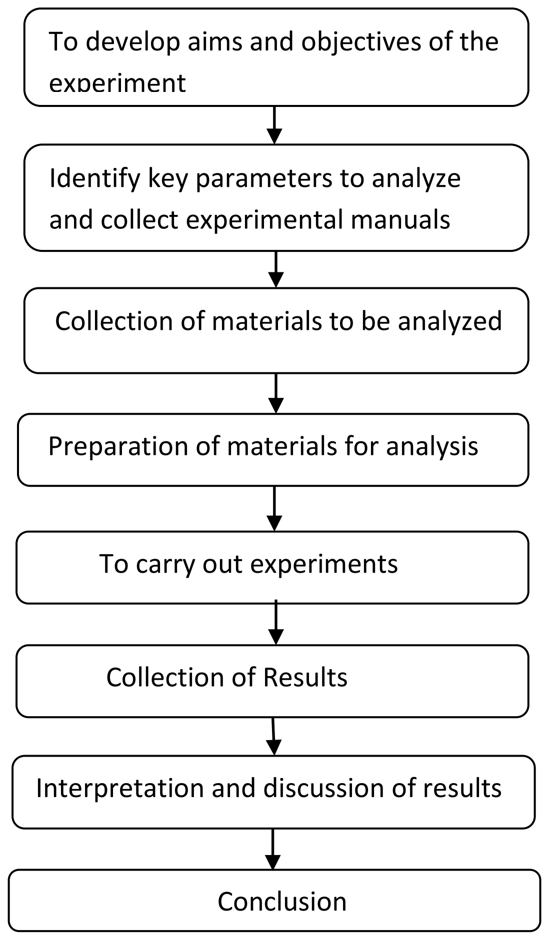


Fig.5.1 Protocol for Analysis of Shoe Upper Materials.

5.4.0 Materials and Methods

With leather being a non-homogeneous material, performance tests have an important role to play in assessing its quality. Depending on the end-use and types of leather, a wide range of tests based on visual, physical and chemical properties could be carried out in a testing laboratory. In this experiment, certain comfort and physical/ performance characteristics of shoe upper leather samples were determined.

Physical properties are determined as per standard methods under specified temperature and relative humidity. Prior to testing, the samples have to be conditioned in a standard atmosphere of 20^{o}C, 65% R. H (relative humidity) for at least 48 hours. To achieve this, a standard laboratory had to be used to conduct the analysis. Therefore the experiments were conducted at the Standards Organization of Nigeria Textile/ Leather Laboratory, Kaduna, Nigeria from May to June, 2013 (see appendix XIII). Samples of shoe upper leather were collected from different leather industries (refer to appendix XIV- S/no. 8-11) for the analysis and standard dimensions for various physical tests were obtained as per the International Union of the Society of Leather Technologist and Chemists Official Methods of Analysis (1996).

Because there can be more than one test method to use for determination of the same basic leather property, table 5.1 gives the different tests carried out, the methods or procedures adopted and the equipment used. Furthermore, a brief explanation on how each of the parameters was determined is provided from sub-section 5.4.1 to 5.4.7.

Table 5.1 Tests conducted and methods of analysis.

S/No.	Test/ Parameter	Method of Analysis	Equipment
1	Determination of thickness of shoe upper material	IUP/4. 1996	Wallace Thickness measurement gauge; Ref:S4/9, Serial No. 82/8. Made in England.
2	Determination of Apparent Density	IULTCS/ IUP 5: 2001	(1).Wallace Thickness measurement gauge; Ref:S4/9, Serial No. 82/8. Made in England. (2). Mettler Weighing balance: Type-AE 200-S. Made in Switzerland.
3	Determination of Water Vapour Permeability	IULTCS/ IUP15: 2001	MUVER-WVP equipment. Mod-5011; No. 01556; 2007.
4	Determination of Absorption of Water	IUP/7	Kubelka apparatus
5	Determination of Tear Strength	IUP/8	SMS material tester. Model SP 2-4300, USA New Jersey.
6	Determination of Tensile Strength & Elongation at Break	BS 2576: 1986/ IULTCS/ IUP 6: 2001	SMS material tester. Model SP 2-4300, USA New Jersey.
7	Determination of grain crack & burst of shoe upper materials	IUP/9	Muver Lastometer equipment. No. 01555; Mod-5077 ET. 2007

Following is a brief description of how the various parameters were determined.

5.4.1 Thickness measurement.

The thickness of the leather specimens was determined using a standard leather thickness-testing instrument (refer to table 5.1 above). The specimens were placed in the instrument and the load was gently applied, and the reading was taken five seconds after the full load was reached. For the greatest possible accuracy, it was ensured that the error did not exceed 0.005.

5.4.2 Apparent Density.

The thickness of each leather sample was measured as prescribed in the method for measurement of thickness (IUP/4). After that, the diameters of the samples were determined in two directions at right angles to one another on both grain surface and flesh surface. The arithmetic mean of the measurements was recorded as the diameter of each sample.

The weights of the samples were determined using mettler balance (see fig. 5.2) and the apparent density was calculated by dividing the mass of the samples in grammes by its volume in cubic centimeters (cm^3).

Fig. 5.2 Mettler weighing balances.

5.4.3 Water vapour permeability/ Absorption.

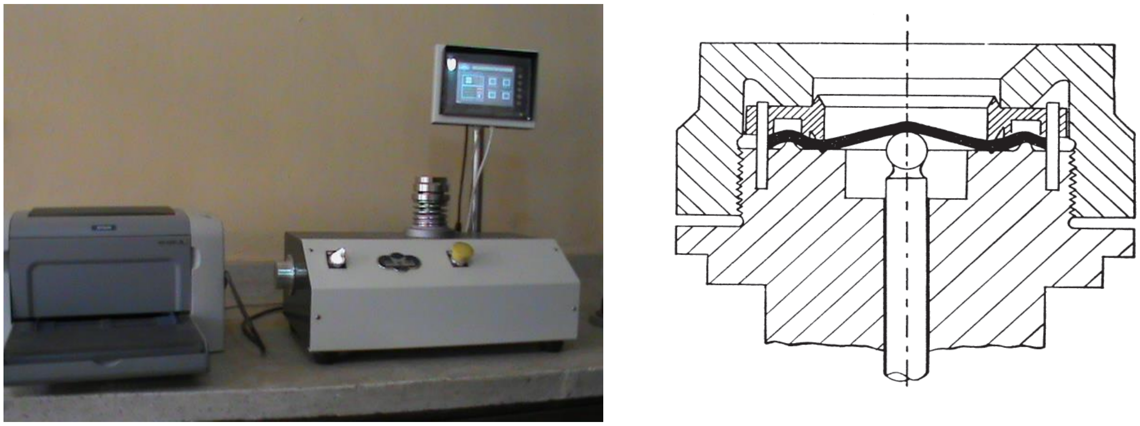
The water vapour permeability (WVP) and water vapour absorption (WVA) were determined using standards WVP/ WVA testing instruments (see fig. 5.3). The initial weights of the samples were determined using a weighing balance. The samples were clamped across the mouth of test jars whose weights were taken, and a known quantity of distilled water was poured inside the jar and weighed again. The samples were clamped on to the instrument that was maintained at a high temperature and had a current of air blowing over the tops of the test units.

At specific intervals of time (1hr, 2hrs, & 3hrs) the jars were carefully removed from the instrument, blotted and the test units weighed at each interval. At such time, any loss of water by transmission through the composite test samples was noted and the amount of water absorbed by the individual pieces was also recorded.

Fig. 5.3 Water Vapour Permeability machine.

5.4.4 Determination of distension and strength of grain by the ball burst test.

A circular test leather sample was prepared and clamped around the edge of the testing machine (see fig.5.4) and force was applied gradually to the specimen by forcing a small metal object attached to the equipment (see fig.5.4a & 5. 4b). During the test, the surface of the specimen was continually observed. The force and the distension of the test material were recorded at the first surface cracking. The force was applied until the specimen busted, and the distension and load at this point were recorded.



(a) (b)

Fig. 5.4 (a) Lastometer Instrument. **(b)** Cross section of clamping head of lastometer with leather sample in position (British Standard 2003, P. 2)

5.4.5 Measurement of the Absorption of Water.

This parameter was determined using the volumetric method. The apparatus (see fig.5.6) was filled to the zero mark with distilled water by running into it 75 ml at 20 ± 2^{0}C. The sample was weighed and placed in the apparatus until it was completely immersed in the water. After the sample was immersed for the required time, the volume of liquid absorbed was measured.

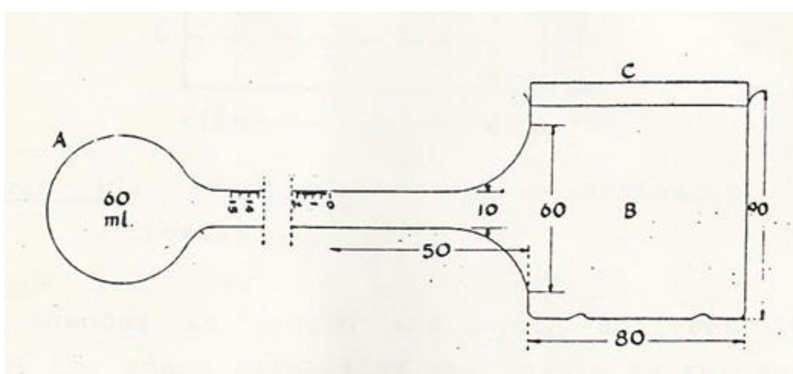


Fig.5.5 Kubelka apparatus (Luijten, 1988; P. 27)

5.4.6 Tensile Strength and Elongation at break.

Tensile strength and elongation samples were taken from adjacent locations of the leather. The width of each sample was taken and the arithmetic mean of the result of six readings was calculated and the value considered as the width of the sample. The thickness of each sample was also measured in accordance with the official method of measurement of thickness (see sub-section 5.4.1). The area of the cross section of each sample was calculated by multiplying its width by its thickness.

The leather samples were then clamped in the jaws of the machine and run until the sample was broken. The highest load reached was taken as the breaking load. The tensile strength was calculated by dividing the breaking load by the area of cross-section of the sample.

The same procedure for the determination of tensile strength was followed to determine the elongation at break of the samples. In addition, the distance between the pair of the jaws at the instant when rupture of the sample occurred was noted. This was taken as the length of the sample at break. The elongation at break was calculated by taking the difference between the initial length and the length at break.

Fig. 5.6 Tensile Strength Machine.

5.4.7 Determination of Tearing Strength.

The Strength machine used to determine tensile strength was used to measure the tearing strength. However, the sample holders were replaced with the type used for tearing load, which consisted of a strip of steel 10mm wide and 2mm thick. The strip of steel bent through at a right angle at one end and welded to a bar that makes the strip rigid. Each sample was fixed on the machine and run until the sample was torn apart. The highest value reached during tearing was recorded as the tearing strength.

5.5.0 Results of the Material Analysis.

Tables 5.2 to 5.8 provide the results of the experimental analysis of different samples of shoe upper materials.

Table 5.2: Result of Determination of Thickness of Shoe Upper Materials (Leather).

Sample		1st Position (mm)	2nd Position (mm)	3rd Position (mm)	Avg. (mm)
	1a	1.26	1.10	1.10	1.15
U_1	1b	1.19	1.12	1.17	1.15
	1c	1.70	1.12	1.15	1.32
Avg. (mm)					**1.21**
	2a	1.90	1.85	1.90	1.88
U_2	2b	1.86	1.84	1.75	1.82
	2c	1.80	1.85	1.75	1.80
Avg. (mm)					**1.83**
	3a	1.90	1.92	1.90	1.90
U_3	3b	1.85	1.90	1.90	1.88
	3c	1.90	1.90	1.87	1.89
Avg. (mm)					**1.89**
	4a	1.92	1.92	1.90	1.81
U_4	4b	1.92	1.90	1.91	1.91
	4c	1.90	1.91	1.90	1.90
Avg. (mm)					**1.87**
	5a	2.15	2.12	2.10	2.12
U_5	5b	2.35	2.50	2.45	2.40
	5c	2.16	2.27	2.12	2.18
Avg. (mm)					**2.23**

Table 5.3: Result of Determination of apparent density.

Sample	Thickness (mm)				Weight (g)				Apparent Density (g/cm^3)
	1	2	3	Avg (mm)	1	2	3	Avg (g)	
U_1	1.15	1.15	1.32	**1.21**	1.92	2.0	1.92	**1.95**	**0.26**
U_2	1.88	1.82	1.80	**1.83**	1.33	1.40	1.40	**1.38**	**0.14**
U_3	1.90	1.88	1.89	**1.89**	1.40	1.54	1.39	**1.44**	**0.15**
U_4	1.81	1.91	1.90	**1.87**	1.20	1.25	1.23	**1.25**	**0.13**
U_5	2.12	2.40	2.18	**2.23**	3.70	3.10	3.90	**3.57**	**0.37**

Calculation: The apparent density (D_a) was calculated using the formula;

$D_a = M\,(g) / \pi r^2 t(cm^3)$

Where:

M = mass of the sample in grammes
r = radius of the sample (cm)
t = height of the sample.

Table 5.4a: Result of Determination of Water Vapour Permeability of Shoe Upper Materials.

Sample		Original Wt. of sample (g)	Sample Wt. + Container (g)	Wt. @ 1hr (g)	Wt. @ 2hr (g)	Wt. @ 3hr (g)	Final wt. of Sample + Container (g)
U_1	1a	1.93	161.10	2.30	2.32	2.32	161.00
	1b	2.00	170.00	2.54	2.55	2.55	159.05
	1c	1.92	163.10	2.50	2.50	2.50	161.10
Avg (g)		1.95	164.73	2.44	2.45	2.45	163.71
U_2	2a	1.33	156.64	1.43	1.44	1.44	155.80
	2b	1.40	153.53	1.47	1.48	1.48	152.50
	2c	1.40	154.60	1.44	1.45	1.45	154.05

Avg (g)		1.37	154.92	1.44	1.45	1.45	154.1
U_3	3a	1.42	156.60	1.99	2.00	2.00	155.70
	3b	1.40	154.33	1.84	1.85	1.85	154.00
	3c	1.41	154.32	1.80	1.81	1.82	153.95
Avg (g)		1.41	155.08	1.87	1.88	1.89	154.55
U_4	4a	1.20	153.86	1.49	1.50	1.51	152.55
	4b	1.22	153.89	1.48	1.49	1.50	151.90
	4c	1.20	152.85	1.43	1.45	1.47	152.10
Avg (g)		1.20	153.53	1.46	1.48	1.49	152.18
U_5	5a	3.70	170.24	4.40	4.42	4.43	170.15
	5b	3.75	170.37	4.35	4.40	4.41	170.24
	5c	3.90	170.53	4.42	4.44	4.45	170.40
Avg (g)		3.78	170.43	4.39	4.42	4.43	170.26

Table 5.4b: Summary of Results of Water Vapour Permeability (WVP) and Water Vapour Absorption (WVA).

Sample	*Wt. loss (mg)*	*Wt. gain (mg)*	*WVP (mg/cm^2/h)*	*WVA (mg/cm^2)*
U_1	1.02	0.50	19.14	28.15
U_2	0.82	0.08	15.39	4.50
U_3	0.53	0.48	9.94	27.02
U_4	1.35	0.29	25.33	16.32
U_5	0.17	0.65	3.19	36.59

Calculation: the WVP was calculated using the formula

$$WVP = \frac{\text{Total weight of water transmitted (mg)}}{\text{Test area in cm}^2 \text{ x Test time (h)}}$$

Whereas, the WVA was calculated from the formula

$$WVA = \frac{\text{Weight gain by material (mg)}}{\text{Material area (cm}^2\text{)}}$$

$$= \frac{\text{Weight gain by material}}{\pi r^2}$$

r = radius of the sample knife.

Table 5.5: Result of Water Absorption of Shoe.

Sample	Initial Wt. (g)	Water Absorption (ml)							Final wt. of sample (g)	Total water absorption (mg)
		15 Min.	30 Min.	45 Min.	1 Hr.	2 Hrs.	3 Hrs.	24 Hrs.		
U_1	2.35	2.10	2.60	3.00	3.00	3.00	3.00	3.20	4.30	1,950
U_2	1.23	2.20	2.40	2.40	2.40	2.40	2.40	2.50	2.48	1,250
U_3	1.30	1.10	2.00	2.00	2.10	2.30	2.30	3.00	3.02	1,720
U_4	1.23	2.00	2.10	2.10	2.30	2.30	2.30	2.50	2.90	1,670
U_5	3.64	0.20	0.50	1.50	2.20	2.50	3.00	3.20	4.75	1,110

Table 5.6: Result of measurement of distension and strength of the grain by the ball burst test.

Sample		Crack		Burst	
		Load (N)	**Displacement (mm)**	**Load (N)**	**Displacement (mm)**
U_1	1a	135.9	10.62	287.7	10.33
	1b	152.3	11.84	305.7	10.59
	1c	289.7	9.83	316.1	10.41
Avg.		**192.63**	**10.76**	**303.16**	**10.44**
U_2	2a	322.7	10.99	337.4	11.15
	2b	262.4	10.75	284.0	11.04
	2c	242.3	9.56	324.8	10.37

Avg.		**275.8**	**10.43**	**315.4**	**10.85**
U_3	3a	464.4	10.27	478.2	10.40
	3b	432.4	10.75	533.6	10.68
	3c	449.0	10.44	496.4	10.79
Avg.		**448.6**	**10.48**	**502.3**	**10.62**
U_4	4a	249.7	8.36	419.7	9.69
	4b	242.6	8.45	391.4	9.68
	4c	167.9	7.99	360.0	9.85
Avg.		**220.0**	**8.26**	**390.3**	**9.74**

Note: The test was not carried out on U_5 because its thickness was above the scope of this test.

Table 5.7: Result of Determination of Tensile Strength (N/mm^2) & Elongation at Break (%).

Sample	**Parallel**				**Perpendicular**			
	Force (N)	**Displ. (mm)**	**% Elong.**	**Tensile Strength (N/mm^2)**	**Force (N)**	**Displ. (mm)**	**% Elong.**	**Tensile Strength (N/mm^2)**
U_1	188.74	33.02	46	15	161.33	34.11	65	13
U_2	95.29	14.91	57	19	67.79	16.78	48	17
U_3	223.39	25.50	61	21	160.66	30.75	81	22
U_4	189.55	30.88	50	17	145.27	19.10	32	14
U_5	488.25	40.41	76	23	459.57	40.56	29	20

Table 5.8: Result of Determination of Tear Strength (N/mm^2).

Sample	Parallel			Perpendicular		
	Force (N)	**Displ. (mm)**	**Tensile Str. (N/mm^2)**	**Force (N)**	**Displ. (mm)**	**Tensile Str. (N/mm^2)**
U_1	57.91	19.07	37	50.89	38.72	35
U_2	23.60	13.00	51	18.21	27.98	52
U_3	47.32	17.61	41	39.71	13.61	39
U_4	44.08	34.32	46	45.54	13.79	45
U_5	237.03	41.13	124	250.00	34.96	119

5.6. 0 Discussion

This experimental analysis provides some insight on how materials' properties can differ significantly one from another, and a careful selection of materials based on their comfort and performance properties have far reaching benefits in terms of foot health. The results of the key parameters investigated are discussed under the following sub- headings.

5.6.1 Comfort properties of shoe upper materials.

Moisture related tests are very useful in determining comfort of shoes made with leather, because during walking, foot temperature increases owing to rubbing between the shoe and foot. At such moments, the skin produces perspiration from sweat glands to reduce the body temperature (Covington 2009; Wilson 2000). The most frequently used test to measure the comfort properties of shoe upper leathers are the water vapour permeability, water absorption, and the dynamic water penetration. In this work, water vapour permeability/absorption and water absorption tests were carried out to assess the comfort properties of the shoe upper leather samples.

Good water vapour permeability properties of shoe upper materials (also known as ventilating properties of leather) help in the dispersal of perspiration and make an important contribution to foot comfort and hygiene. This is an important factor of consideration because footwear has its interior in close contact with a mobile, warm and perspiring part of the human foot while its exterior may be subjected to cold, heat, rain, very dry air, snow or wet grass (Xiaosheng 2012; Mohammad 2003; Kanagy 1977). It can be explained as the ability of a material to transmit water from one side to the other in the form of vapour. On the other hand, water vapour absorption refers to how much of that vapour is retained by absorption within a material structure. In other words, absorption of water vapour is the ability of a material to take and hold moisture. The material holds the moisture by its molecular structure and the water cannot be physically squeezed out before its saturation with moisture. Tailby, et al (2002, p.12) put it this way:

> "Absorption may be considered a 'stand alone' moisture disposal mechanism because it is not dependent upon any other factors for comfort, at least in the short-to-medium term. However, once the absorption capacity of materials is reached (saturated) water will remain as a liquid and the foot will become damp and uncomfortable".

According to the SATRA (1999) water vapour permeability test method, if the water vapour permeability of a test material is higher than 5.0mg/cm/h, then it is classed as having 'very good' permeability for footwear. But Harvey (1992) states that a permeability value of 2mg/cm^2/h is recommended for satisfactory foot comfort. It has been shown that this factor (comfort) along with the ability to shape to the foot, has been the main reason for choice of leather for shoes. But comfort is a complex perception that relies on many sensations. With respect to moisture disposal, absorption by the upper materials is perhaps as important as the permeability—because this will ensure that the wearers' feet remain dry (Rose, et al. 1992; Thorstensen 1993).

From the above explanation and the summary of the results of the water vapour permeability/ absorption of the test samples shown in tables 5.4a & 5.4b, all the leather samples have met the minimum required standard, but some have better water vapour permeability/ absorption than others. The result of sample U_4 and U_1 with values of 25.33mg/cm/h and 19.14mg/cm/h respectively are considered very excellent. Samples U_5 and U_3 have the lowest values of 3.19 and 9.94mg/cm/h respectively.

Covington (2009) and Thorstensen (1993) explain that one of the most desirable properties of leather is its ability to transmit moisture. However, its properties depend on the origin of the raw material, how the pelt is prepared for chemical modification, how that modification is conferred chemically, how the leather is lubricated and how the surfaces are prepared. Previous research reported that the water vapour permeability (WVP) of coated leather (e.g with PU) decrease by 30-50% compared with uncoated or unfinished leather. To improve wear comfort and hygienic properties of shoe upper materials, leather coating with very high WVP has become very important (Yi et al. 2010). In addition, to achieve high foot comfort, footwear uppers should be made from thinner skins of calf or split cowhides and should be tanned with chrome, which does not fill the pores (Kanagy 1977).

Everyone accepts that the comfort provided by leather articles is linked to leather ability to combine breathing and insulating properties. Whereas leather may pass water vapour through but resist liquid water penetration, the same thing cannot be said about synthetic materials that usually give negative results in regards to water vapour permeability. The implication of this is that most synthetic materials do not allow water vapour to pass through. Good air and vapour permeability of leather is because of the numerous pores found both in the fibrous network and between the collagen molecules (Phebe et al. 2010, Tagang 2010; Covington 2009). The ability of leather to transmit water vapour is one of the key properties which make it a desirable material for footwear construction. The leather takes out perspiration from the foot by absorption, which is followed by evaporation from the footwear. This usually leads to increased comfort for the wearer.

As already known, footwear and clothes should be water vapour permeable to be comfortable. The permeability of leather allows perspiration to be transmitted promptly when activity level increases in order to avoid a damp and over-heated feeling. It is concluded that the higher the permeability of the upper material the better its ventilating property.

5.6.2 Fundamental physical properties.

The thickness of a piece of leather sample can differ significantly if the approved test method (as explained in 5.4.1) is not maintained. It is recognized that measured thickness of leather depends upon such factors as the pressure and the time for which pressure is applied. Having carried out the thickness measurement in accordance with the prescribed method, it was found out that sample U_5 has the highest average value (2.23mm) and sample U_1 has the lowest average value of 1.21mm (see table 6.2). It was observed that the thickness of a leather sample has appreciable influence over other determined parameters.

Beside thickness property, another basic physical parameter of the material studied is the apparent density. The density of a substance is the mass per unit volume of the substance, as for example, gm/cm^3. However, the true volume of leather is difficult to measure accurately because it has many different sized pores. Therefore, when the volume of leather is calculated without taking into account the pores, the ratio of the mass to the volume is known as the apparent density. When the volume of the pores is considered, the value obtained is known as the real density. The apparent density of leathers differ one from another based on the pore volume of each one. For example, a heavily rolled sole leather may have an apparent density of 1.15, whereas a porous leather such as buckskin may have an apparent density of 0.52. The type of filler used to fill some of the pores could also affect the apparent density (Chukwuma & Kuye 1995; Kanagy 1977).

In this analysis, it was discovered that the apparent density of the tested materials range from 0.13 to 0.37. Since the apparent density of a material gives an estimate of the fibres and air spaces in a material, it then means that sample U_5 has more air spaces compared with the result obtained for sample U_4 (see table 6.3). In connection with some recent work on the comparative apparent density of different types of leather, Clarke (2010) reported that the apparent densities of leathers vary widely. Cowhide leathers may be grouped approximately as follows: vegetable tanned sole leather range from 0.95-1.05, vegetable tanned leather other than sole leather range from 0.80 to 0.90, and unwaxed chrome-tanned leather range from 0.60 to 0.70. It therefore implies that the values obtained for this present work are low when compared with the results other types of leathers obtained by Clarke (2010).

5.6.3 Performance properties.

The tensile strength test gives a reliable indication of the quality of shoe upper materials. Strength is an indication of fiber quality. Therefore, low strength indicates degradation or low fiber quality (www.astm.org/standards/d2209.htm). It is an important consideration in the evaluation of leather. It can be expressed in terms of "force per unit cross sectional area" as commonly done in engineering materials or it can be expressed in "force per inch of width" as it is in textiles.

Leather has a difference in strength in the length and width direction. According to Volken (2013), leather has two directions of stretch, strong or tight along the direction of the backbone and weak or loose across the belly. The tensile strength is generally greater when it is determined in a direction parallel to the backbone because the orientation of the fibers is predominately in this direction. In addition, leather has a difference in these characteristics, depending upon the section of the hide from which it is cut. To make a pair of footwear that fits correctly, the upper patterns must therefore seek to accommodate these physical constraints and the proportions of the human foot. Furthermore, material with good stretchability has been shown to adjust to feet easily (Bata 2013).

The data from this study shown in table 5.7 indicates that the values of the tensile strength obtained by the parallel measurements were observed to be generally higher than the corresponding values for the perpendicular. This is consistent with information from literature (Volken 2013; Marsal 2004). The highest tensile strength recorded in this experiment is 23N/mm^2 which corresponded to sample U_5 and the lowest is 15N/mm^2 (corresponding to sample U_1). Contrary to tensile strength, the highest values for percentage of elongation at break are higher in the perpendicular direction than in the parallel direction. From table 5.7 it is clear that the highest percentage of elongation is 81% (U_3, perpendicular) and the lowest value is recorded against sample U_5. The elongation for light upper leathers may range from 10-30% that for heavy leathers is in the range of 35-85%. Any value below this indicates poor fiber quality or degradation. This present experiment values fell between 29 to 81%.

Besides the tensile strength measurement, the tear strength of the specimens was carried out. It is considered a good guide to understanding the quality of a material because it takes thickness of a material into account. In addition, the grain crack/ burst test was carried out by applying pressure on the leather sample until cracking of the grain occurred. The load and distension registered gives a measure of the leather's resistance. This test is used to know the force required to break the grain of upper leather. One of the key advantages to using this test is that it gives an average value for the strength of a material in all directions. To keep grain cracking in lasting to a minimum, the average distension of new, unlasted leather should be at least 7 mm.

5.7 Chapter Summary.

The choice of footwear material significantly influences foot comfort. In this study, leather samples were analysed to show how physical properties of upper leathers can differ appreciably one from another. Beside comfort properties like water vapour permeability/ absorption, some performace properties like tensile strength, tear strength, and leather basic physical properties (that is, thickness and apparent density) were determined. Generally, the results obtained were found to be similar to the outcome of previous studies and in conformity to set standards. This study further shows that a thorough knowledge of the physical properties of materials used for making footwear would help to identify materials that would improve comfort and safety to the wearer.

In this chapter, the researcher demonstrates that diabetic footwear should be made of leather which has properties of particular value in respect to foot health. The excellent virtues of leather for making footwear include its ability to allow air and water vapour to pass through the cross section of the upper. However, the viability of using other new materials as alternatives is also noted. Therefore, in respect to foot health and safety, the use of any material for footwear manufacture that would engender a feeling of comfort when the footwear is worn should be further explored. In addition, the author suggests that further investigations using composite specimens of both upper and lining, soling materials and insoles to establish the best material combination that may improve foot health should be looked into. The next chapter provides another important aspect of this study; that is foot measurement and determination of tolerable allowance.

Chapter 6: Foot Measurement and Determination of Tolerable Allowance

6.1 Introduction

The relation between foot shape and shoe shape is considered a cause of discomfort, foot problems, or even injury because an individual's shoe size and foot size can differ significantly. Also, foot morphology differs appreciably based on geographic area of an individual origin (Olivato et al. 2007; Hawes 1994; Goonetilleke 2003). Therefore, to be able to make shoes to an individual's correct shoe size and to eliminate guess work, accurate measurement of the foot is required.

Many people assume they know their correct shoe size, but previous studies show that a careful consideration of the relationship that exists between the foot shape and the lasts is required in order to be able to make comfortable shoes for the wearer. Furthermore, to provide the best fit of footwear for the diabetic population, correct measurement of their feet before they buy shoes must be carried out (Olivato 2007; Goonetilleke 2003).

With this understanding, the present study was undertaken in Nigeria to provide the researcher with data that would be useful for the construction and assessment of diabetic footwear prototypes (refer to the next chapter). In addition, the results of the foot survey would provide the footwear and last makers with important information that would allow them to make model sizes of lasts on which the desired standard diabetic footwear could be made. Therefore, this chapter provides information on materials and devices used for foot measurement, results of measurements taken at crucial positions of the foot and the implications of the variations that exist in the dimensions of an individual's feet.

6.2.0 Aim and objectives of this chapter.

6.2.1 Aim

The aim of this study is to carry out foot survey using simple measuring techniques in order to determine tolerable allowance of Nigerians' feet.

6.2.2 Objectives

The objectives of the study presented in this chapter are:

- To study human foot shape and dimensions.
- To measure the feet of research participants from Nigeria in order to determine their footwear tolerable allowance.
- To use the findings for effective explanation of the concept of proper footwear fitting in the next chapter.
- To provide recommendations for acceptable foot tolerable allowance for diabetic patients in Nigeria.
- To identify areas that would require further research.

6.3.0 Protocol for foot measurement

Figure 6.1 provides a summary of the protocol followed to collect the required information presented in this chapter.

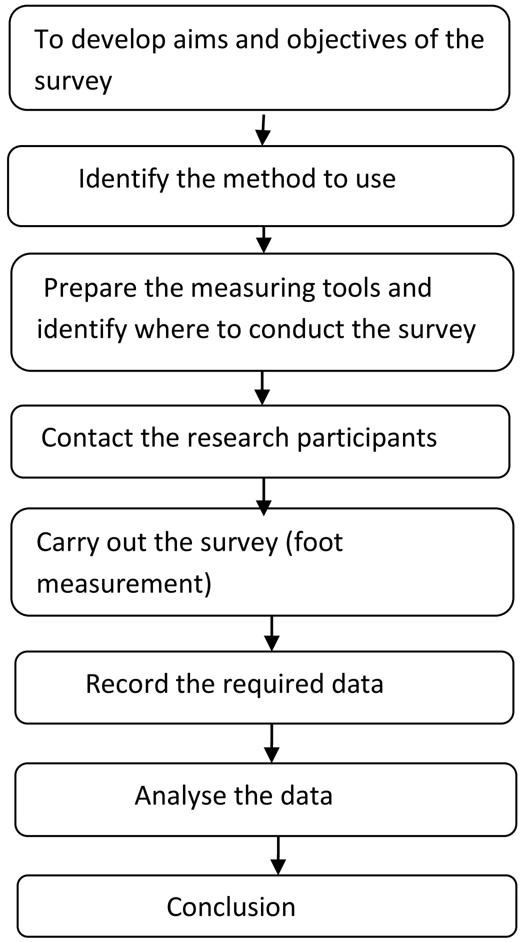


Fig.6.1 Protocol for foot measurement.

6.4.0 Materials and Method

6.4.1 Materials

As pointed out in chapter 2 (sub-section 2.10.1) there are many devices that could be used to measure the foot for last/ footwear design and fitting. These devices range from simple measuring tape to sophisticated equipments like laser scanning devices that can record thousands of measurements of the whole foot. The different devices or tools are designed to take accurate and specific measurements of important positions of the foot. It has been shown that "taking foot measurement could be as simple as using a last maker's tape measure, or as complex as the hand-drawn chart for a bespoke item or the use of the latest computer-aided design/ computer-aided manufacturing (CAD/CAM) scanning system that records hundreds of measurements in a split second to reproduce a three-dimensional image on the computer screen" (Tyrrell & Carter 2009, p.76/77). In this survey, the following simple materials and tools were used to carry out the foot measurement.

- Pencil
- Ruler
- Measuring tape
- White sheets of paper (A4)

6.4.2 Method or Procedure

This research was carried out with simple but accurate tools and procedures. In general, there are two kinds of approaches for measuring the foot shape. One is the measurement of static foot shape, and the other is about the motion dynamics of the foot. It has been pointed out that static foot shape is needed to design appropriate footwear (Kimura et al. 2009). Therefore, in this study, the approach that was adopted is the static foot measurement and the steps followed are hereby outlined.

Step 1

In a standing position, the participant placed his or her foot on a clean white A4 sheet of paper. Taking the foot measurement while the subject stands up allows the foot to be measured at its maximum length and width. For correct measurement to be obtained, it was ensured that the feet of the subjects were placed on the paper at 90^{o} to the leg. This position is considered semi-weight bearing, which means that there is some pressure through the foot (Broussard 2002).

Step 2

A pencil was used to trace around the foot of the participant gently and ensuring that the pencil remained in constant contact with the foot during the process. To ensure that the measurement carried out would allow for foot comfort and ample room, it was done in the afternoon/ evening because some people's feet swell, especially after standing for long periods of time.

Step 3

The positions of the inner and outer ball joint (1^{st} and 5^{th} metatarsals) were marked. Also, the position of the longest toe was marked with a pencil.

Step 4

The circumference of the foot at the in-step was measured with a measuring tape. Two measurements were made at this point. Firstly, the circumference of the foot was accurately measured, and afterward, the second reading was taken after the tape was pulled and the subject indicated that it was too tight. This is a very important measurement as it was used to determine the tolerable allowance of the research subjects by subtracting the second reading of the in-step measurement from the first.

Step 5

To find the overall length, the distance between the two longest points on the tracing was measured. Similarly, the width was found by measuring the distance between the two widest points (usually at the 1^{st}/ 5^{th} MTP joint) on the tracing using a ruler that was clearly calibrated in millimeters. Each measurement was recorded immediately on a prepared sheet of paper.

6.5 Results of foot measurements.

In this survey, 280 normal adult volunteer subjects were involved. Of this number, 186 (66%) were male and 94 (34%) female (see table 6.13 and 6.14). While tables 6.1 to 6.6 provide detailed results of the male participants, tables 6.7 to 6.12 give the full results of the female subjects. The data gathered from the subjects were grouped based on their shoe size. For instance, men wearing shoe size 40 were coded M_A and female wearing shoe size 36 were coded F_A.

Table 6.1 Results of foot measurement: Men wearing shoe size **40.**

Male Subjects	**Age (yrs)**	**Foot Length (mm)**		**Foot Width (mm)**		**In-step Girth (mm)**		**Tolerable Allowance (mm)**
		Right	**Left**	**Right**	**Left**	**1st**	**2nd**	
M_A01	55	252	250	97	102	245	242	3
M_A02	37	242	237	104	98	246	244	2
M_A03	46	249	246	93	95	235	230	5
M_A04	32	245	242	89	90	233	231	2
M_A05	*DNM	255	254	98	98	234	232	2
M_A06	22	238	239	88	86	210	207	3
M_A07	23	254	253	102	100	240	235	5
M_A08	47	254	255	103	103	263	258	5
M_A09	29	251	254	100	98	238	235	3
M_A10	25	249	248	95	95	229	226	3
M_A11	32	246	250	110	108	248	245	3
M_A12	40	244	246	96	96	265	263	2
M_A13	75	245	237	104	100	255	252	3
M_A14	40	242	247	86	95	257	253	4
M_A15	45	245	239	95	102	245	241	4
M_A16	18	250	248	88	83	220	215	5
M_A17	23	247	247	93	93	242	239	3
M_A18	30	241	245	83	85	230	228	2
Mean age (yrs	**36.4**							
Avg (mm		247.1	247.5	95.7	95.9	240.8	237.5	**3.3**

*DNM - Do not want to mention.

Table 6.2. Results of foot measurement: Men wearing shoe size **41.**

Male Subjects	**Age (yrs)**	**Foot Length (mm)**		**Foot Width (mm)**		**In-step Girth (mm)**		**Tolerable Allowance (mm)**
		Right	Left	Right	Left	1st	2nd	
M_B01	35	258	260	102	100	240	237	3
M_B02	53	259	258	100	103	265	261	4
M_B03	35	264	255	99	104	260	255	5
M_B04	54	266	265	102	100	270	266	4
M_B05	25	256	261	95	97	260	255	5
M_B06	27	259	254	100	96	260	253	7
M_B07	25	250	250	92	85	242	240	2
M_B08	23	258	255	98	98	236	233	3
M_B09	43	265	265	95	94	260	256	4
M_B10	23	256	262	102	102	253	248	5
M_B11	67	259	255	98	95	250	248	2
M_B12	25	254	253	103	99	250	245	5
M_B13	26	258	262	102	100	248	245	3
M_B14	23	250	255	97	95	251	248	3
M_B15	57	263	271	99	103	240	238	2
M_B16	52	255	248	98	96	252	249	3
M_B17	75	260	251	104	106	258	255	3
M_B18	DNM	255	254	96	99	255	253	2
M_B19	64	250	246	96	96	230	225	5
M_B20	DNM	265	268	97	92	241	236	5
M_B21	62	257	256	95	96	240	238	2
M_B22	67	260	254	90	92	235	230	5
M_B23	52	265	260	103	98	242	238	4
M_B24	55	262	262	102	101	246	242	4
Mean age (yrs)	**44.0**							
Avg (mm)		258	257.4	99	98.4	249.3	245.6	**3.7**

Table 6.3. Results of foot measurement: Men wearing shoe size **42.**

Male Subjects	**Age (years)**	**Foot length (mm)**		**Foot Width (mm)**		**In-step Girth (mm)**		**Tolerable Allowance (mm)**
		Right	Left	Right	Left	1st	2nd	
M_C01	57	260	267	107	106	258	256	2
M_C02	48	269	269	100	99	260	258	2
M_C03	23	267	266	103	103	240	235	5
M_C04	22	270	273	100	101	240	237	3
M_C05	20	260	255	95	96	230	225	5
M_C06	34	260	261	99	100	240	237	3
M_C07	29	260	258	100	100	253	248	5
M_C08	45	272	270	99	105	249	246	3
M_C09	25	265	270	102	96	257	254	3
M_C10	42	265	265	110	110	290	285	5
M_C11	32	259	260	110	109	275	270	5
M_C12	27	256	257	94	94	270	268	2
M_C13	21	266	267	105	103	257	254	3
M_C14	47	277	276	106	105	276	270	6
M_C15	33	280	279	106	104	258	256	2
M_C16	53	272	269	102	97	265	263	2
M_C17	44	270	274	107	109	268	265	3
M_C18	44	262	256	104	99	265	262	3
M_C19	29	277	267	102	100	245	240	5
M_C20	25	266	270	96	96	252	249	3
M_C21	37	268	267	95	95	260	255	5
M_C22	23	262	265	102	98	260	255	5
M_C23	30	275	271	98	100	255	252	3
M_C24	23	277	277	92	95	255	253	2
M_C25	43	261	263	100	99	257	254	3

M_C26	47	264	265	100	101	261	258	3
M_C27	26	267	268	104	104	242	239	3
M_C28	32	268	268	105	105	250	245	5
M_C29	20	265	266	104	99	253	249	4
M_C30	45	280	285	109	108	280	275	5
M_C31	20	272	268	102	105	270	265	5
M_C32	40	265	265	100	100	245	240	5
M_C33	25	269	261	100	97	240	235	5
M_C34	24	260	263	94	95	230	228	2
M_C35	38	269	270	100	97	260	258	2
M_C36	25	267	272	110	108	251	248	3
M_C37	58	269	267	105	107	288	285	3
M_C38	18	280	280	120	115	270	266	4
M_C39	25	266	266	98	100	243	240	3
M_C40	23	262	258	92	90	225	222	3
M_C41	22	273	275	103	100	242	240	2
M_C42	22	277	272	105	110	235	233	2
M_C43	22	278	280	98	95	240	237	3
M_C44	23	280	280	115	114	262	257	5
M_C45	22	275	277	116	110	270	267	3
M_C46	21	285	288	104	107	252	248	4
M_C47	30	269	269	98	98	240	237	3
M_C48	21	267	266	93	96	270	267	3
M_C49	20	258	264	103	98	271	268	3
M_C50	30	268	266	87	87	241	237	4
M_C51	20	262	259	99	95	250	247	3
M_C52	50	260	258	96	91	253	250	3
M_C53	60	268	264	92	93	232	228	4
M_C54	71	268	273	106	107	265	262	3
M_C55	53	271	267	100	103	280	277	3
M_C56	54	264	266	106	105	262	259	3

M$_C$57	48	265	246	101	96	270	267	3
M$_C$58	80	265	273	107	103	272	268	4
M$_C$59	23	274	271	102	108	260	255	5
M$_C$60	76	257	257	91	92	235	231	4
M$_C$61	75	254	258	89	86	235	232	3
M$_C$62	62	274	270	107	109	263	259	4
M$_C$63	63	265	266	108	103	261	258	3
Mean age (yrs)	**36.3**							
Avg (mm)		267.873	267.6	98.2	97.5	255.6	252.1	**3.5**

Table 6.4. Results of foot measurement: Men wearing shoe size **43.**

Male Subjects	**Age (yrs)**	**Foot Length (mm)**		**Foot Width (mm)**		**In-step Girth (mm)**		**Tolerable Allowance (mm)**
		Right	Left	Right	Left	1st	2nd	
M$_D$01	25	273	273	102	101	250	245	5
M$_D$02	40	280	278	108	110	287	284	3
M$_D$03	30	272	275	105	107	266	263	3
M$_D$04	41	279	277	108	113	295	290	5
M$_D$05	33	268	274	108	108	281	277	4
M$_D$06	23	278	276	108	110	271	268	3
M$_D$07	45	275	280	107	105	270	266	4
M$_D$08	33	288	287	105	102	270	265	5
M$_D$09	38	282	283	106	103	270	265	5
M$_D$10	33	288	285	102	106	280	278	2
M$_D$11	43	282	280	108	102	272	269	3
M$_D$12	40	267	261	99	98	265	250	15
M$_D$13	22	267	267	98	98	267	260	7
M$_D$14	37	285	283	96	97	250	247	3

M_D15	28	267	267	109	109	300	296	4
M_D16	24	282	278	105	104	270	263	7
M_D17	46	275	280	96	98	280	278	2
M_D18	38	288	284	109	109	268	266	2
M_D19	29	278	273	100	97	255	252	3
M_D20	30	277	278	107	104	270	268	2
M_D21	41	272	272	101	102	267	265	2
M_D22	29	275	277	102	104	265	262	3
M_D23	42	275	276	110	111	280	275	5
M_D24	30	277	271	101	95	240	235	5
M_D25	27	285	285	105	105	275	272	3
M_D26	30	273	278	110	112	271	267	4
M_D27	50	277	277	115	115	295	290	5
M_D28	22	279	285	103	105	265	261	4
M_D29	21	268	263	90	94	250	248	2
M_D30	24	273	274	106	110	275	273	2
M_D31	27	274	270	106	108	255	251	4
M_D32	36	272	265	104	97	268	264	4
M_D33	34	270	270	93	94	251	247	4
M_D34	24	289	285	114	115	270	268	2
M_D35	38	273	280	105	110	270	267	3
M_D36	28	285	280	107	102	268	266	2
M_D37	19	280	285	115	110	267	265	2
M_D38	32	285	283	115	111	270	264	6
M_D39	41	292	286	116	117	300	294	6
M_D40	36	265	272	100	100	255	250	5
M_D41	27	263	264	93	94	260	257	3
M_D42	31	281	280	104	103	270	265	5
M_D43	45	275	280	113	106	261	257	4
M_D44	65	262	260	101	101	252	248	4
Mean age (yrs)	**33.6**							
Avg (mm)		276.6	276.3	104.9	104.6	269.0	265.0	**4**

Table 6.5 Results of foot measurement: Men wearing shoe size **44.**

Male Subjects	**Age (yrs)**	**Foot Length (mm)**		**Foot Width (mm)**		**In-step Girth (mm)**		**Tolerable Allowance (mm)**
		Right	Left	Right	Left	1st	2nd	
M_E01	24	282	283	103	105	280	278	2
M_E02	42	290	290	110	110	290	288	2
M_E03	46	286	286	120	112	285	281	4
M_E04	34	285	283	111	105	279	276	3
M_E05	31	288	291	105	108	272	269	3
M_E06	47	293	293	110	109	273	270	3
M_E07	51	285	288	108	110	283	280	3
M_E08	40	300	301	113	105	285	281	4
M_E09	29	272	276	103	103	251	247	4
M_E10	40	275	275	114	116	280	277	3
M_E11	33	288	287	110	111	255	253	2
M_E12	35	285	285	119	119	282	279	3
M_E13	30	290	291	117	117	300	295	5
M_E14	40	275	278	110	111	290	287	3
M_E15	23	272	271	95	94	271	268	3
M_E16	25	298	300	130	122	295	292	3
M_E17	26	265	265	93	100	265	261	4
M_E18	39	285	285	114	106	265	261	4
M_E19	27	271	277	104	100	267	265	2
M_E20	23	286	265	96	96	250	246	4
M_E21	26	277	276	98	100	260	257	3
M_E22	28	278	281	90	102	254	252	2
M_E23	40	261	265	95	97	282	279	3
M_E24	45	286	281	107	109	268	264	4
M_E25	53	271	280	100	100	273	270	3

M_E26	27	270	267	101	101	269	267	2
M_E27	52	275	261	103	108	275	271	4
M_E28	70	286	282	117	113	274	271	3
M_E29	47	290	284	104	106	268	266	2
Mean age (yrs)	**37.0**							
Avg (mm)		281.6	280.9	106.9	106.7	273.8	270.7	**3.1**

Table 6.6 Results of foot measurement: Men wearing shoe size **45/46½**

Male Subjects	**Age (yrs)**	**Foot Length (mm)**		**Foot Width (mm)**		**In-step Girth (mm)**		**Tolerable Allowance (mm)**
		Right	Left	Right	Left	1st	2nd	
M_F01	26	297	296	108	105	280	277	3
M_F02	37	292	295	110	103	282	278	4
M_F03	36	291	300	113	112	290	288	2
M_F04	24	300	295	108	105	300	297	3
M_F05	37	297	297	110	105	281	278	3
M_F06	39	287	287	115	116	275	272	3
M_F07	21	315	318	120	122	302	299	3
M_F08	58	286	291	112	110	292	290	2
Mean age (yrs)	**34.7**							
Avg (mm)		295.6	297.4	112	109.8	287.8	284.9	**2.9**

Table 6.7. Results of foot measurement: women wearing shoe size **37**.

Female Subjects	**Age (yrs)**	**Foot Length (mm)**		**Foot Width (mm)**		**In-step Girth (mm)**		**Tolerable Allowance (mm)**
		Right	Left	Right	Left	1st	2nd	
F_A01	50	238	232	93	92	210	205	5
F_A02	29	211	244	92	90	228	225	3
F_A03	32	238	238	93	93	225	220	5
F_A04	60	245	240	87	85	210	205	5
F_A05	20	230	228	95	92	220	215	5
F_A06	20	236	237	85	87	230	227	3
F_A07	23	238	240	96	98	231	228	3
F_A08	19	249	254	96	95	240	238	2
F_A09	18	240	244	85	87	230	227	3
F_A10	16	244	246	93	97	238	233	5
F_A11	23	232	225	80	74	220	216	4
F_A12	35	242	247	100	94	240	235	5
F_A13	25	234	234	86	86	231	226	5
F_A14	22	230	225	82	80	220	217	3
F_A15	26	240	240	84	84	240	237	3
F_A16	20	232	237	85	82	230	226	4
F_A17	25	254	251	90	93	223	220	3
Mean age (yrs)	**27.3**							
Avg (mm)		237.24	238.9	89.5	88.8	227.4	223.5	**3.9**

Table 6.8. Results of foot measurement: women wearing shoe size **38.**

Female Subjects	**Age (yrs)**	**Foot Length (mm)**		**Foot Width (mm)**		**In-step Girth (mm)**		**Tolerable Allowance (mm)**
		Right	Left	Right	Left	1st	2nd	
F_B01	21	242	246	88	86	240	237	3
F_B02	21	249	256	98	96	235	230	5
F_B03	17	234	235	80	86	215	205	10
F_B04	19	252	254	79	81	220	215	5
F_B05	18	246	231	88	85	235	230	5
F_B06	33	247	250	98	103	230	228	2
F_B07	29	249	244	90	91	217	214	3
F_B08	30	238	242	89	92	221	218	3
F_B09	32	246	248	93	87	244	240	4
F_B10	60	246	247	88	88	242	238	4
F_B11	22	247	254	102	100	240	237	**3**
F_B12	35	244	244	110	108	240	235	5
F_B13	25	242	245	100	100	238	233	5
F_B14	22	248	254	88	90	236	231	5
F_B15	16	240	240	83	88	240	237	3
F_B16	20	242	239	88	84	250	246	4
F_B17	28	240	245	98	95	271	268	3
F_B18	25	241	245	99	95	240	234	6
F_B19	22	250	252	85	90	242	238	4
F_B20	24	244	245	79	79	241	239	2
F_B21	23	237	238	91	88	243	240	3
F_B22	24	248	247	95	94	235	232	3
F_B23	25	235	233	94	94	234	230	4
Mean age (yrs)	**25.6**							
Avg (mm)		243.7	244.9	91.4	91.3	236.8	232.8	**4**

Table 6.9. Results of foot measurement: women wearing shoe size **39.**

Female Subjects	**Age (yrs)**	**Foot Length (mm)**		**Foot Width (mm)**		**In-step Girth (mm)**		**Tolerable Allowance (mm)**
		Right	Left	Right	Left	1st	2nd	
F_C01	26	263	260	92	92	242	238	4
F_C02	21	260	267	102	99	245	241	4
F_C03	24	242	240	88	84	240	238	2
F_C04	30	263	257	95	100	230	227	3
F_C05	23	248	250	88	87	243	240	3
F_C06	19	250	253	97	92	230	228	2
F_C07	18	248	248	91	90	225	223	2
F_C08	55	246	253	88	97	235	230	5
F_C09	20	249	243	88	80	237	235	2
F_C10	21	241	242	90	91	250	248	2
F_C11	22	260	260	96	97	238	234	4
F_C12	21	248	250	96	92	251	248	3
F_C13	20	248	237	91	88	230	228	2
F_C14	23	249	244	91	93	237	234	3
F_C15	18	255	255	95	95	243	238	5
Mean age (yrs)	**24.0**							
Avg. (mm)		251.3	250.6	92.5	91.8	238.3	235.3	**3**

Table 6.10. Results of foot measurement: women wearing shoe size **40.**

Female Subjects	**Age (yrs)**	**Foot Length (mm)**		**Foot Width (mm)**		**In-step Girth (mm)**		**Tolerable Allowance (mm)**
		Right	Left	Right	Left	1st	2nd	
F_D01	32	268	261	88	88	251	248	3
F_D02	23	253	250	85	78	234	230	4
F_D03	32	268	267	104	96	256	253	3
F_D04	23	261	260	100	100	238	235	3
F_D05	38	275	272	112	112	270	265	5
F_D06	DNM	256	251	88	93	235	232	3
F_D07	48	240	267	100	103	244	240	4
F_D08	43	267	265	100	95	240	237	3
F_D09	DNM	253	249	95	91	242	238	4
F_D10	DNM	258	265	95	98	250	247	3
F_D11	DNM	253	249	96	95	252	250	2
F_D12	DNM	245	243	90	83	260	257	3
F_D13	25	256	256	91	91	242	238	4
F_D14	26	265	263	95	89	250	246	4
F_D15	47	258	264	113	110	230	225	5
F_D16	23	262	262	104	105	265	260	5
F_D17	DNM	246	242	88	83	251	249	2
F_D18	23	257	260	101	100	239	236	3
F_D19	DNM	254	248	88	87	250	246	4
Mean age (yrs)	**31.9**							
Avg (mm)		257.6	257.5	96.4	94.5	247.2	243.7	**3.5**

Table 6.11. Results of foot measurement: women wearing shoe size **41.**

Female Subjects	**Age (yrs)**	**Foot Length (mm)**		**Foot Width (mm)**		**In-step Girth (mm)**		**Tolerable Allowance (mm)**
		Right	Left	Right	Left	1st	2nd	
F_E01	21	251	235	97	88	243	240	3
F_E02	61	261	258	90	94	251	248	3
F_E03	25	245	237	89	86	234	230	4
F_E04	21	268	271	108	105	247	243	4
F_E05	24	260	260	95	86	260	256	4
F_E06	DNM	250	256	97	95	261	259	2
F_E07	20	273	270	104	100	255	252	3
F_E08	27	260	260	100	98	241	238	3
F_E09	24	252	252	90	88	250	247	3
F_E10	27	256	255	104	102	262	259	3
F_E11	24	250	254	100	96	242	238	4
Mean age (yrs)	**27.4**							
Avg (mm)		256.9	255.2	97.6	94.3	249.5	246.3	**3.2**

Table 6.12. Results of foot measurement: women wearing shoe size **42.**

Female Subjects	**Age (yrs)**	**Foot Length (mm)**		**Foot Width (mm)**		**In-step Girth (mm)**		**Tolerable Allowance (mm)**
		Right	Left	Right	Left	1st	2nd	
F_F01	21	262	259	90	87	261	258	3
F_F02	22	265	265	95	91	260	257	3
F_F03	25	259	258	88	90	263	260	3
F_F04	DNM	260	261	97	96	260	258	2
F_F05	DNM	252	245	96	92	264	260	4
F_F06	29	258	262	91	90	225	220	5
F_F07	26	278	278	97	104	252	249	3
F_F08	DNM	247	245	88	96	290	287	3
F_F09	29	265	272	105	102	257	254	3
Mean age (yrs)	**25.3**							
Avg (mm)		260.6	260.5	94.1	94.2	259.1	255.9	**3.2**

Table 6.13 Summary of Outcome of foot measurements (male subjects).

Subjects (Shoe sizes)	**Mean age (years)**	**No**	**%**	**In-step Girth (mm)**		**Tolerable Allowance (mm)**
				1st reading	**2nd reading**	
M_A (40)	36.4	18	10	240.8	237.5	3.3
M_B (41)	44.0	24	13	249.3	245.6	3.7
M_C (42)	36.3	63	34	255.6	252.1	3.5
M_D (43)	33.6	44	24	269.0	265.0	4.0
M_E (44)	37.0	29	15	273.8	270.7	3.1
M_F (45/$46^{1}/_{2}$)	34.7	08	4	287.8	284.9	2.9
Avg (mm)				**262.7**	**259.3**	**3.4**

Table 6.14 Summary of outcome of foot measurements (female subjects).

Subjects (Shoe Size)	Mean age (years)	No	%	In-step Girth (mm)		Tolerable Allowance (mm)
				1st reading	2nd reading	
F_A (37)	27.3	17	18	227.4	223.5	3.9
F_B (38)	25.6	23	24	236.8	232.8	4.0
F_C (39)	24.0	15	16	238.3	235.3	3.0
F_D (40)	31.9	19	20	247.2	243.7	3.5
F_E (41)	27.4	11	12	249.5	246.3	3.2
F_F (42)	25.3	9	10	259.1	255.9	3.2
Avg (mm)				**243.0**	**239.5**	**3.5**

The average tolerable allowance for both male and female participants was found to be **3.45mm.**

6.6.0 Discussion

The summary of the outcome of the foot measurements for both genders based on their shoe size is presented in figure 6.2 below. The chart indicates that up to 34% of male subjects wear shoe size 42, making it the most popular size among the male subjects. This is followed by size 43 with 24% subjects. On the other hand, shoe size 38 is the most widely worn by the female subjects with up to 24% participants. This is closely followed by those wearing size 40 with a value of 20%. The mean age of all male subjects was found to be 37.0 and for female subjects, the mean age was 26.9.

The results of the foot measurements carried out are discussed under three sub-titles namely; length, joint girth or width and in-step. According to Tyrrell & Carter (2009), these are the first basic measures used by clinicians to determine the type of footwear needed to meet the patient's requirements. It is generally noted that the outcome of the right and left foot measurement of most individuals differ one from another. Similarly, the results of the foot dimensions of those wearing the same shoe size varies one from another. These findings are in complete agreement with the research outcome of Broussard (2002) that indicates that most people's feet are two different sizes.

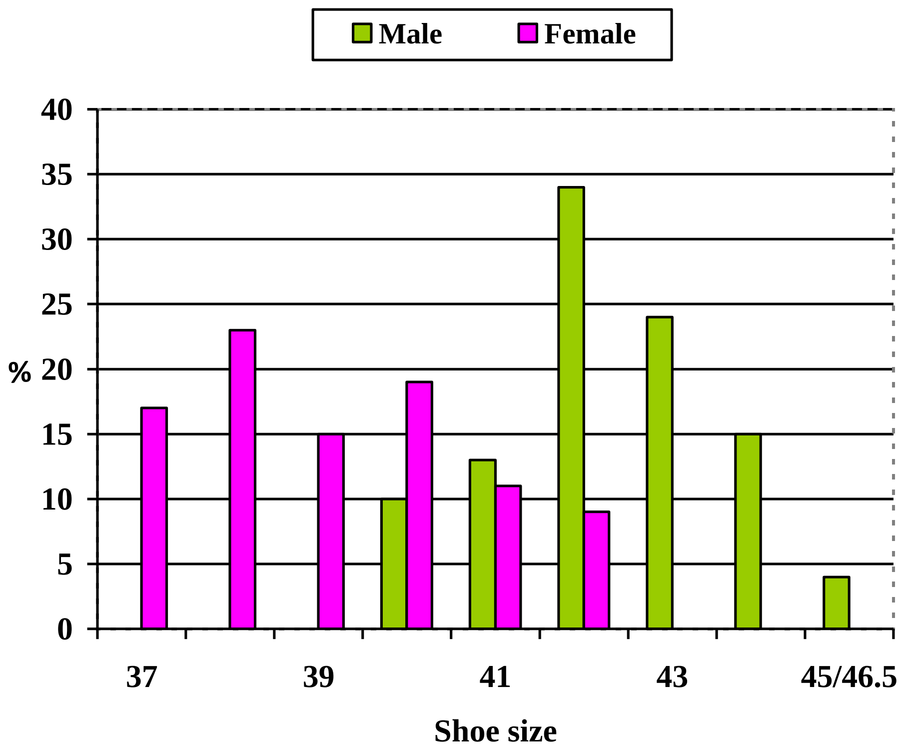


Fig.6.2 Participants' shoe size.

6.6.1 Foot Length.

It is clear from the outcome of this survey that very few people have the same foot length for both the right and the left foot. The difference in some people's foot length can be negligible whereas the difference may be appreciable among others. Such differences can be clearly observed in table 6.5 and 6.7 where a difference of up to 14mm and 33mm was recorded against subjects M_E27 and F_A02 respectively. The differences in foot dimensions (length) recorded in this study for subjects wearing the same shoe size are up to 21mm (refer to subject M_B19 and M_B15, table 6.2). In like manner, up to 20mm difference in width exist between subjects M_A06 and M_A11. These differences can become a source of serious foot discomfort for the subjects when such differences were not taken into consideration. A study conducted by Pezza (2011) reported that it is rare to find a diabetic patient who is wearing the proper shoe size and width. He argues that there is a direct correlation between recurrent foot problems and improper footwear. The current findings are in complete agreement with this argument.

Tyrrell and Carter (2009) further point out unequivocally that all feet are different. They explained that even if the whole shoe length is correct, but the heel-to-ball length (see fig.6.3a) of the footwear does not correspond with the heel to MTP (metatarso-phalangeal) joint measurement of the foot, the foot flexion will not be able to meet the point the shoe is designed to flex. Generally, comfortable footwear should be designed in such a way that it can accommodate the longest part of the foot. It should also be noted that the longest part of the foot differs one from another. Mostly, the hallux is longer than the other toes but in some patients, one or more of the other (lesser) toes may be longer than the hallux (see appendix XV for different shape of foot outlines). It is generally advisable that patients wear footwear that are large enough to provide room for changes in dimension of the foot that may occur during walking or sitting for long periods of time. Although there is need for additional space in the footwear to allow for the elongation of the foot during the stance phase of the gait cycle, the amount of space may not be more than 1cm or 0.5 inch. However, there is no fixed rule for the amount of free or extra length required at the end of the toe box. But in general, research has shown that men tend to wear footwear that are too large and women the opposite (Pezza 2011).

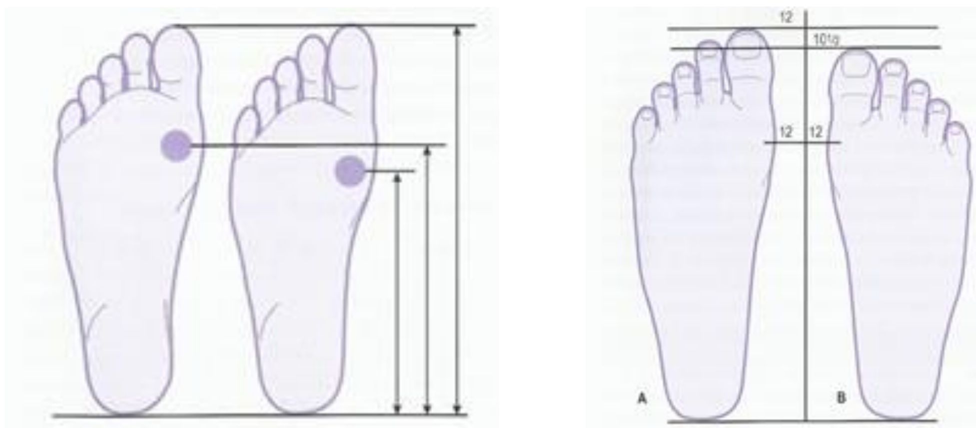
It should be noted that individuals could have the same overall foot length but different heel-to-ball length and some could also have the same heel-to-ball length but different overall length (see fig. 6.3a & fig.6.3b). For the comfort of the wearer, it is important that footwear for the diabetic foot should be designed to flex at a specific angle across the 1st to 5th metatarsals joints. In other words, the flexion angle within the footwear should match the angle between the 1st and 5th metatarsal heads of the foot. It has been reported that two thirds (2/3) of diabetic patients wear poor fitting footwear, but that shoes designed for people suffering with diabetes could reduce re-ulceration rates by half (Leese 2009).

6.6.2 Foot Width.

The length of the foot/ footwear as discussed above is only but one feature that should be critically considered; the other measurement that should be taken into account to provide footwear that fits well includes the width (particularly, the joint width; see fig. 6.4). Similar to foot length, it was discovered that there are variations between the width of an individual's feet as well as among people wearing the same shoe size. However, the differences in the foot width are not as wide-ranging as the differences recorded for foot length. This research shows that the difference in foot width could be up to 12mm as recorded in Table 6.5 (M_E22). Measurement of this part of the foot is considered very important because the MTP (metatarsal phalangeal) joints are seen as the most complicated parts of the foot because their shape changes during walking and standing positions. In addition, it has been suggested that the width of the footwear should be adequate to accommodate orthoses in case a patient needed to wear them, and that proper fastening to hold the foot and to avoid rubbing should always be put in place (Chen 1992).

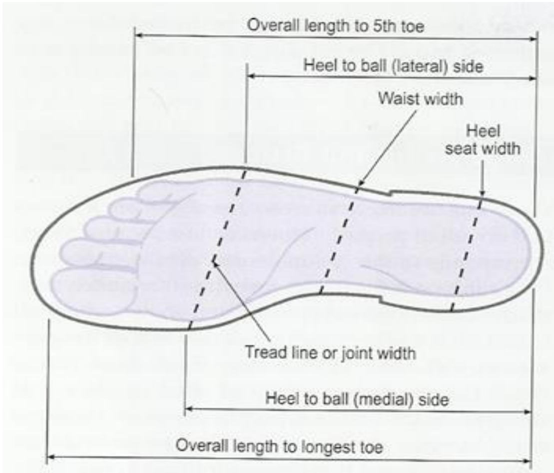
Research has shown that a normal foot will usually expand by about 5% over the course of a day. This equals to one shoe size in volume. But where there is circulatory problem (for instance, neuropathy), the foot could expand up to 10% during the day. This could cause considerable pressure and swelling inside the shoe which could lead to development of pressure lesions and injury (Tyrrell & Carter 2009).

According to Tyrrell and Carter (2009), footwear width corresponds with length. However, patients with wide feet tend to choose footwear that is too long for them so as to obtain their required shoe width. This can cause negative effects on the foot because it means that the MTP joints will be positioned proximal to the footwear tread line and the footwear flexion will not correspond to foot flexion which could lead to creases on the vamp. To ensure that the foot and the footwear bend together, prescription footwear must be designed in such a way that the 1st metatarsal joint or ball joint fits to the widest part where the footwear flexes across the metatarsal heads from 1st to 5th.

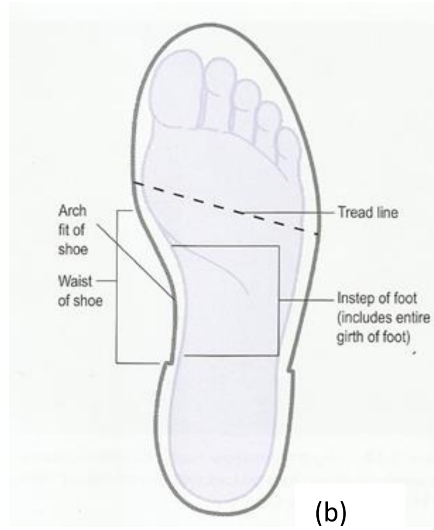


(a) (b)

Fig. 6.3 (a) Feet with same overall length but different heel-to-ball measurement. (b) Feet with different overall length but same heel-to-ball measurement (Tyrrell & Carter 2009, p.66).



(a)



(b)

Fig. 6.4 (a) Sketch of a foot showing joint width. (b) Sketch of a foot showing In-step of foot (Tyrrell & Carter, 2009. p.67/72).

6.6.3 In-step girth and tolerable allowance.

As mentioned in sub-section 6.6.1, the in-step measurement is very important in determining suitable footwear for people at risk of developing foot ulcers. The in-step refers to the whole girth of the foot around the arch and onto the dorsum (see fig.6.4b). There could be significant differences of this part of the foot from one individual to another, even people wearing the same shoe size. A typical example can be seen in table 6.3 where we have a difference of up to 20mm between subjects M_C02 and M_C03 even though they wear the same shoe size.

This work revealed that some people have low instep which may cause considerable stress on the shoe arch fit. In such a case, it is advisable that the patient uses orthoses in order to improve shoe fit and function. It was also observed that some people's feet have a high instep. Similar to low in-step, footwear fit could be compromised. Therefore, the space may be insufficient to accommodate the foot and the facings will not be able to meet correctly across the fastening of the footwear which will be evident as the facings will be pulled too far apart.

In respect to the foot tolerable allowance, this study indicates that the average tolerable allowance for the male subjects fell between 2.9mm to 4.0mm (see table 6.13) and 3.2mm to 4.0mm values were recorded for the female participants (see table 6.14). The average tolerable allowance for both men and women subjects was found to be 3.45mm.

The analysed data for tolerable allowance of the subjects based on their shoe sized are provided as figure 6.5. The graph indicates that men wearing shoe size 43 gives an average value of 4mm tolerable allowance whereas those using shoe size 38 has the highest average value of 4.0mm. The implication of these values for shoe fitting is discussed in the next chapter.

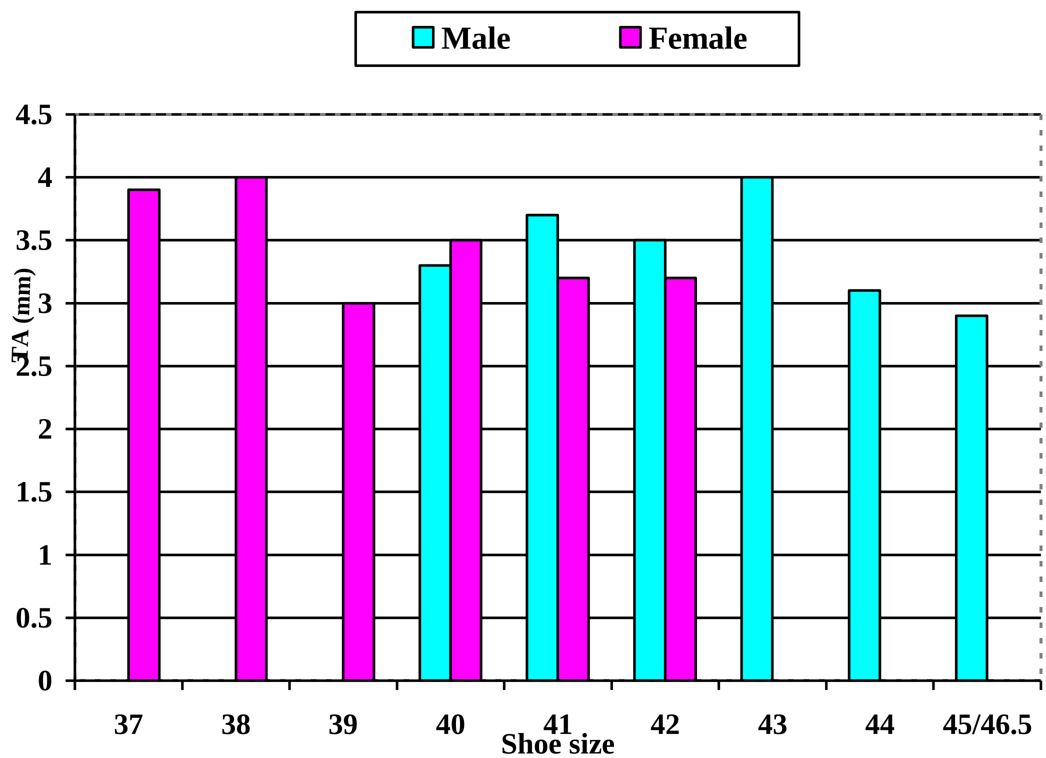


Fig.6.5 Tolerable allowance of subjects according to their shoe size.

6.7 Chapter Summary.

The work of this chapter demonstrates that accurate foot measurement is required to be able to make comfortable footwear for an individual (particularly diabetic patients). The data provided in this study clearly show that very few people have the same foot length and width for both right and left foot. The difference in some people's foot length can be negligible whereas some people's foot length and width could be appreciable. It was also discovered that whereas some people have low in-step which may cause a lot of stress on the shoe arch fit, some have high in-step which could also lead to a compromise in footwear fitting. A typical example can be seen in table 6.3 where we have a difference of up to 20mm between subjects M_C02 and M_C03 even though they wear the same shoe size.

In this study, simple but accurate tools and procedures were used to gather the data. The basic foot dimensions (that is length, joint girth or width and in-step) used by clinicians to determine the type of footwear needed to meet the patient's requirements were recorded and analysed. For future work, the author recommends the use of more advanced technological equipment like laser scanning devices that can record hundreds of measurements of specific important positions of the foot.

Chapter 7: Prototypes Development and Assessment

7.1 Introduction

Research has shown that footwear plays an important role in the prevention and management of diabetic foot problems, but that poor fitting and non-compliance to recommended footwear among people suffering with diabetes is a cause for concern. It was also discovered that a major problem is the rejection of certain footwear due to cultural, cost and aesthetic reasons (Nather & Singh 2008). In view of this, the present work was undertaken to investigate acceptable footwear that could benefit people suffering with diabetes in Nigeria. Firstly, the aim and objectives of the study were formulated, secondly, Product Design Specification (PDS) was developed for the study and thirdly, sketches of footwear were made and presented to potential users to indicate their preferred style, and finally, three functional prototypes were produced based on the PDS and trial assessment carried out.

As clarified by Polydoras et al. (2011), a prototype is an artifact or model that enables designers to test various aspects of their ideas before committing themselves to the expense and risk of producing commercial quantities. The process of building or making this pre-production model to test various aspects of its design is considered as prototyping. A prototype can be used to discover issues about a product or project and to test various aspects of its design or prove a strategic approach (Udell 2013). The prototyping is meant to provide the designer with insight and information about different aspects of product technical attributes, grouped into three main areas; form, fit and function. Therefore, the prototypes were used to evaluate the aesthetics, fit, form, ergonomics, and performance of the product. The models or prototypes were also used to verify acceptability of the product from potential users.

Based on their ability to serve the discrete stages of the design process, prototypes are generally categorised into the following broad prototyping classes (Udell 2013; Eujin 2009 & Barge 2008)

- Design/ aesthetic prototypes, or design/ appearance models. These types of models are mostly concerned with the physical or the external outlook without taking into consideration any functional features.

- Geometrical prototypes. These have all or most of the exact form features and dimensions of the product.

- Functional prototypes. These are described as having similar or the exact material as the final product. They are used to investigate functional concepts of a product including yield and performance factors. For this study, functional products (sandals) are used to show important functional parameters of the products.

- Technical/ technological prototypes. These are usually produced with similar or the exact production method and prototype tooling, where the focus is on attributes of the tools during manufacturing of the product.

- Pre-production models. These are mainly used to fine-tune parameters of the production methods and processes. They are also seen as final design models used to check a product and its finishing as a whole and to carry out production assessment in small batches.

But another categorisation of prototypes according to Eujin (2009) and Ullman (2003) are; visual prototypes such as sketches or drawings, screen-based prototypes, models that are physical representations of a product, and fully working or functional prototypes. Researchers (Ullman 2003; Frishberg 2006) point out that models are better suited during the early stages of development of a product for problem solving and idea generation, whereas prototypes are employed towards the later stages to confirm and assess the aesthetics, ergonomics and performance of the design.

In this study, twelve different footwear designs or sketches were produced based on the results of the empirical study carried out by the author in the previous chapters. The top 3 styles from the 12 designs were developed into functional prototypes that enabled the researcher to test the various aspects of his design concepts among diabetic patients in

Nigeria. The prototyping and assessment of the products provided the researcher with insight and information on different aspects of the preferred footwear styles, features and attributes from potential users of the products. The chapter ends with a brief discussion on the findings of the prototype trials and assessment.

7.2.0 Aim and Objectives of this chapter.

7.2.1 Aim

The aim of this chapter is to develop appropriate diabetic footwear designs and prototypes based on empirical studies.

7.2.2 Objectives

The specific objectives of this study are:

- To identify the most preferred type of diabetic footwear design for people suffering with diabetes in Nigeria.
- To study the preferred type of shoe upper materials for making diabetic footwear.
- To study the type of footwear fastening most preferred by people suffering with diabetes.
- To make diabetic footwear prototypes based on information gathered from research subjects.
- To evaluate the diabetic footwear prototypes produced.
- To provide recommendations for acceptable types of diabetic footwear.
- To identify areas for further research.

7.3 Protocol for this study.

Figure 7.1 provides a flow chart of the protocol used to carry out the work presented in this chapter.

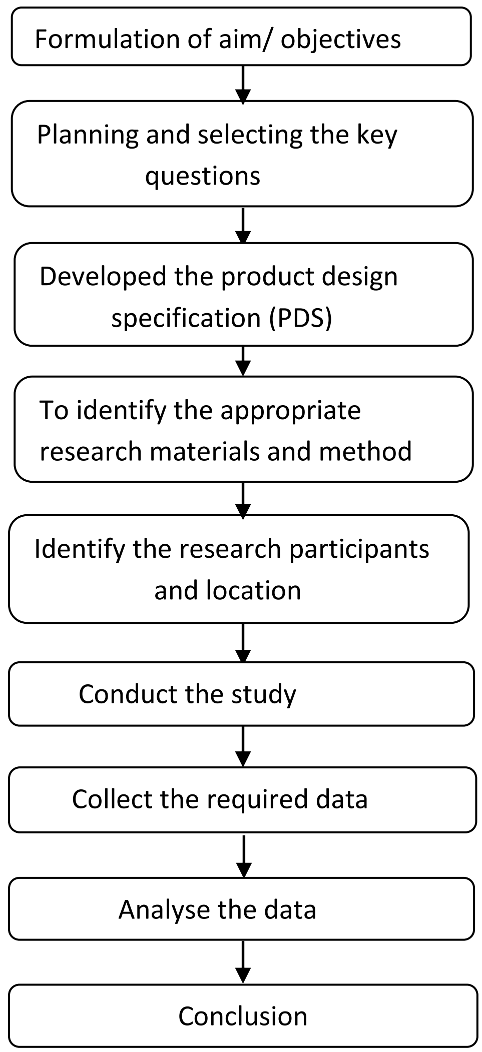


Fig. 7.1 Protocol for testing of diabetic footwear prototypes.

7.4.0 Materials and methods.

7.4.1 Materials.

The shoe upper materials (leathers) used to make the prototype were given to the researcher free of charge for the purpose of this study by some leather industries in Nigeria (see appendix XIV). The contribution of those companies are hereby acknowledged and appreciated. Other simple materials and tools used to carry out this study include the following:

- Pencil
- Ruler
- Measuring tape
- White sheets of paper (A4)
- Velcro
- Fibre board
- Gum
- Rings
- Leather Linings
- Micro cellular soling materials
- Wedge

In addition to the above mentioned materials and tools, a pair of last was used to make the trial prototypes. The appropriate last was selected from a pool of different lasts at the footwear department of Nigerian Institute of Leather and Science Technology (NILEST), Zaria, Nigeria after consultations with the research supervisors and footwear designers/ technologists at the above mentioned Institute. Figures 7.2, 7.3, and 7.4 give pictures of the different views of the lasts, measurement of the last and the last with lasted prototypes respectively. While figure 7.5 shows the bottom outline of the last, table 7.1 gives the dimensions and other features of the last.

Fig. 7.2 Different views of last used for making of prototypes.

Fig. 7.3 Pictures of last measurement.

Style 1 Style 2 Style 3

Fig. 7.4 Last with lasted prototypes (Sandals).

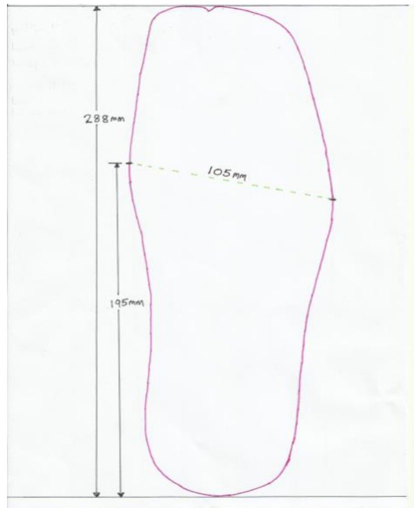


Fig. 7.5 Outline of last used for making the footwear prototypes.

Table 7.1 Last dimensions and features**.**

S/No.	*Parameter*	*Dimensions/ Features*
1	Last number	210106
2	Size	8
3	Colour	Green
4	Overall length (mm)	288
5	Heel to ball Length (mm)	195
6	Width (mm)	105
7	Circumference at In-step (mm)	280

7.4.2 Methods

First and foremost, a standard operating procedure (refer to appendix XVI) for sampling the opinion of the research subjects and testing of Trial Prototype was developed and used for the study.

Twelve styles of footwear designs were initially developed based on certain features and information gathered from questionnaire and interview surveys among diabetic patients and medical doctors respectively (see chapter 3 & 4). Recommendations given by previous authors on required features for diabetic footwear were also taken into account during the design of the present designs. Figure 7.6 gives the different styles of the footwear designs. The designs were presented to diabetic patients (n=43) to indicate their preferred footwear style using a questionnaire (the questionnaire is provided in this thesis as appendix XVII).

In addition, the views of the respondents about the 12 styles (see figure 7.6 & 7.7) were analysed and the top 3 most preferred footwear styles were developed into trial prototypes. Real prototypes which could be described as functional prototypes or high-fidelity prototypes were made for this study. The shoe upper materials were analysed (refer to chapter 5) to determine whether or not they met the minimum basic requirements in terms of physical properties for making diabetic footwear. Other materials (soling materials, lining, insole and other accessories) used for the construction or making of the prototypes were sourced from footwear materials shops in Nigeria. Traditional methods of making footwear (sandals) were used to make the prototypes as outlined in appendix XVIII. Photos of the different stages during the construction of these prototypes are also provided as appendix XIX.

A pencil was used to draw design lines on the last after covering it with masking tape. As usual, the cover was separated from the last and was unfolded onto cardboard paper for making of the design patterns. The patterns were used to cut the upper leather and the lining. The closing of the uppers was carried out with two different sewing machines, namely SIMAC S120U53, serial number 603714Z (2006) and S195505 serial number 010701005 (2001). The lasting of the sandals was done using the same lasts used to design the prototypes. Fortuna, model 65 UD/ID, serial number 2775 are the details of the lasting machine. Other making processes like sole preparation and attachment were all carried out at the above mentioned Institute (NILEST) footwear workshop. See figure 7.2 for different views of the last.

To evaluate the prototypes, a questionnaire was designed (see appendix XX) and was used in conjunction with the prototypes to carry out the trial. The results of the evaluation of the prototypes are presented below (in sub-section 7.7.2).

7.5 Product Design Specification (PDS).

For clarity of the design and construction of the trial prototypes, a product design specification (see pg. 351) was developed as presented below (in table 7.2).

Table 7.2 Product Design Specification (PDS)

S/No.	***Parameters***	***Specifications***
1	Product	Diabetic Footwear (Sandals).
2	Product user	The target users of the product are people living with diabetics in Nigeria and neighboring Africa countries.
3	Gender	Male and female
4	Age Group	Diabetic patients of age group 36- 65 years.
5	Materials selection or short listed materials	Upper Components**:** Good water permeability materials (mainly heavy leather for the upper and light leather or fabric for the lining).
		Insole: Multi-density Ethylene vinyl acetate (EVA) and, or Polyurethane (PU).
		Sole and Heel: Ethylene vinyl acetate (EVA) and, or Polyurethane (PU).

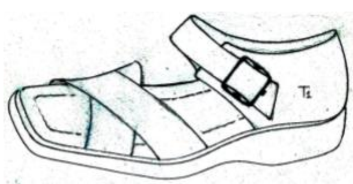
6	Construction	• Select an appropriate last, or make the required last (particularly if there is foot deformation) based on recorded measurements of the customer's feet. • Create the footwear style and the pattern pieces • Close the upper sections • Attach the insole component to the last • Pull down the prepared upper onto the last • Skive excess leather, add bottom filler and attach sole/ heel unit • Remove last and carry out quality checks on the finished product.
7	Special features	• No or low heel height • Functional fastening to minimize compaction of fore foot • Flexible soling with adequate cushioning properties • Firm sole, but not rigid • Very soft, minimal or seam-free full leather linings • Firm upper material • Highly comfortable footwear with high level breathability or good ventilation, long lasting cushioning and light weight footwear.
8	Comfort and Ergonomics	• To make the footwear comfortable for the wearer and to prevent the diabetic footwear from sliding around on the feet, the upper should be designed in such a way that it can be easily adjusted to fit. • The product should be designed ergonomically taken into consideration the fact that some diabetic patients can have problem with their sight and a significant number of them might have neuropathy or numbness. Therefore, the design should be simple in order to make it very easy for the customers to use.

9	Environment	The prospective product users would be people living with diabetics in Nigeria and probably, in other Africa countries. The weather in Nigeria is generally hot year-round. It is hot and dry most part of the year in the North and hot and humid in the South. The average temperatures are: 27-34^{O}C during the day and 23-27^{O}C at night.

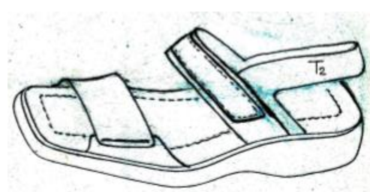
7.6.0 Assessment and Results

7.6.1 Results of Initial survey on preferred footwear style.

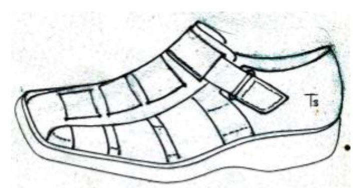
The initial survey on preferred footwear style was carried out among diabetic patients (n=43). Figure 7.6 gives the different footwear styles presented to the research participants to indicate their preferred choice and the outcome of the survey is shown from figure 7.7 to figure 7.12.



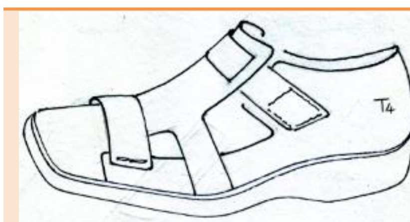
Style 1



Style 2



Style 3



Style 4

Style 5

Style 6

Fig.7.6. Different footwear styles presented to diabetic patients to indicate their preferred style.

The above footwear sketches or designs (fig.7.6) were presented to potential users to select their most preferred style. Among the male participants, the outcome of the survey indicates that style number 3, 1, and 2/7 have the highest percentages of 41.17, 23.53 and 11.76% respectively. But for the female participants, their views on the different styles show that style number 2 with a score of 29.41% is the most preferred (see fig. 7.7).

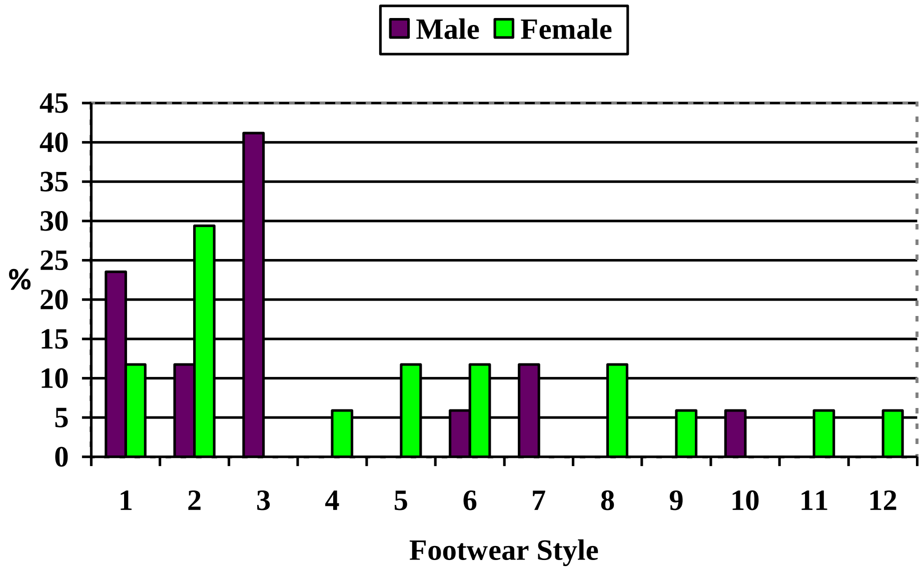


Fig. 7.7 Preferred footwear style.

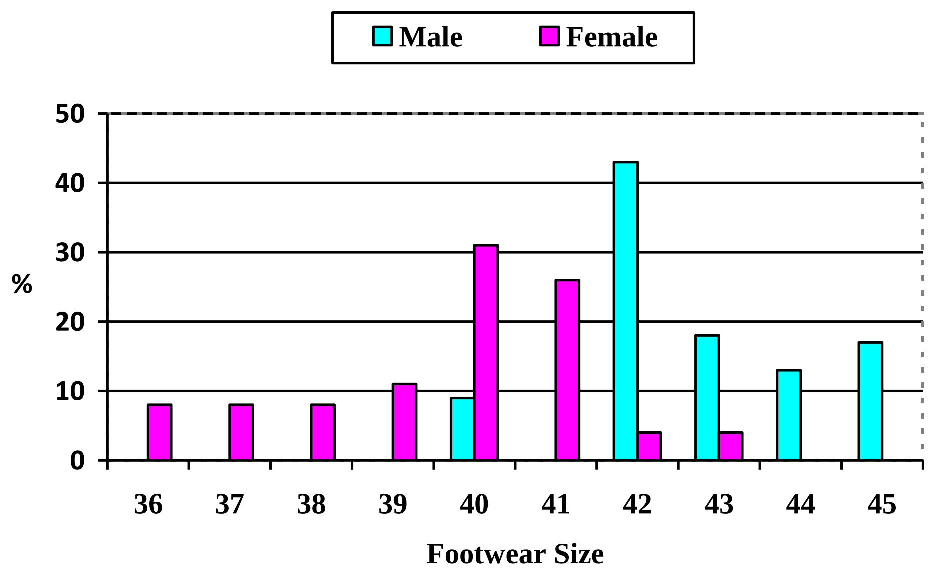


Fig. 7.8 Subjects' Footwear sizes.

To understand the most popular shoe size, the participants were asked to indicate their shoe size during the survey. The findings presented in figure 7.8 clearly show that size 42 is the most popular (43%) men's shoe size. The result for the female indicates that up to 31% used size 40.

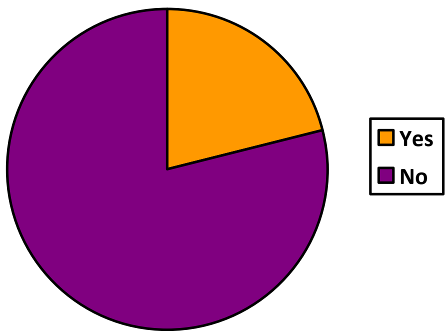


Fig.7.9 Participants with or without foot problem.

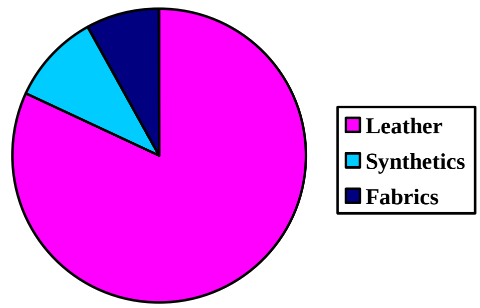


Fig. 7.10 Preferred upper material (Prototype)

Foot problem was another important issue that was considered during the initial survey. The findings given in figure 7.9 provides that up to 21% of the participants were suffering with one form of foot problem or the other and 79% did not have any foot problem at the time of carrying out the study. In respect to preferred shoe upper materials, up to 82% participants preferred leather. The preference for synthetics and fabrics is very low; 10% and 8% respectively (see fig. 7.10).

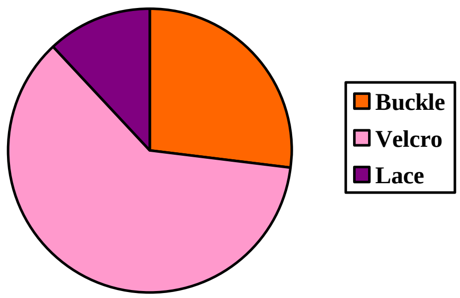


Fig.7.11 Preferred footwear fastening system

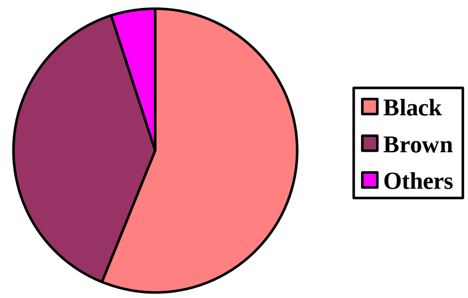


Fig. 7.12 Preferred colour

Due to the importance of fastening system in the construction of diabetic footwear, the views of the subjects were sought about their preferred fastening system. This study clearly shows (fig. 7.11) that up to 61% would like to use footwear made with a velcro fastener. As seen in figure 7.12, it is obvious that the most popular colour is black. Nonetheless, an appreciable percentage (39%) of the subjects would prefer the colour of their footwear to be brown.

7.6.2 Result of Assessment of trial prototypes

The top 3 footwear styles presented in figure 7.13 were developed into functional prototypes. A questionnaire (see appendix XX) was also developed and a validation test was first and foremost carried out with a small sample size (n=10). The result of the pre-test is provided in this thesis as appendix XXI. Following the selection, evaluation and validation of the prototypes, the actual assessment of the prototypes was carried out. The prototypes were presented to the potential users (n=37) to indicate the particular type they liked the most and to try it on their feet. The majority (46%) of the participants preferred style 1 (see fig.7.15). This is contrary to the outcome of the initial survey given in figure 7.7 where we have style 3 as the most popular choice with a score of 41%. But the result of this final assessment is consistent with the outcome of the pre-test which also gives a very high score (50%) for style 1 (refer to appendix XXI). Therefore, the author would like to argue that using functional prototypes to assess a product from prospective users provides better and more reliable views about the product when compared with using sketches, print-out or other formats of prototypes representations. However, materials and colour preference remain the same (refer to fig.7.10, 7.12 and 7.16). Other findings on the assessment of the prototypes are presented below.

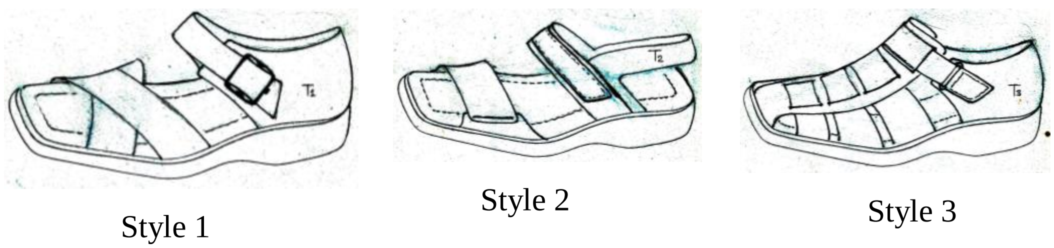


Fig.7.13 Top 3 footwear styles developed into trial prototypes.

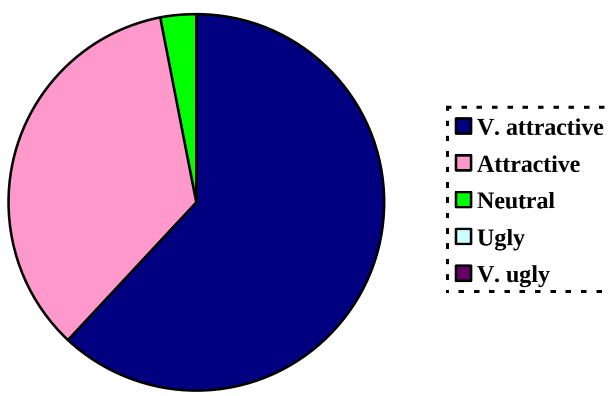


Fig. 7.14 Outcome of visual assessment of the prototypes.

A visual assessment of the prototypes demonstrates that the footwear styles were very appealing and attractive. Only 3% of those that participant in the survey indicated that the products were neither attractive nor ugly. Interestingly, none reported that the prototypes were ugly.

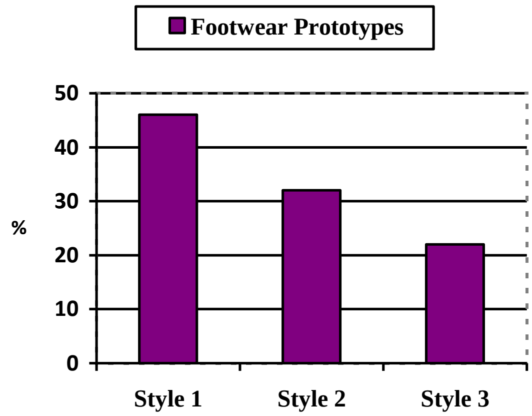


Fig.7.15 Most preferred footwear style

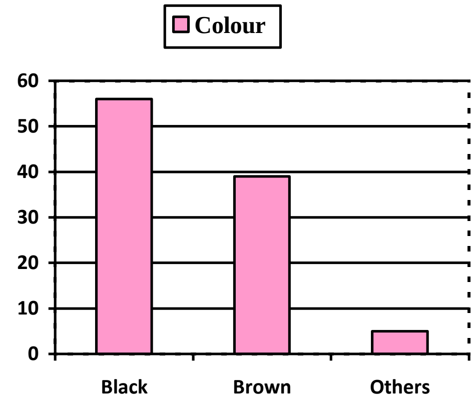


Fig. 7.16 Preferred colour

Table 7.3 Outcome of fit and comfort assessment of the trial prototypes.

S/No.	*Enquiry*	*Yes (%)*	*No (%)*
1	Sandals go onto your feet easily.	86	14
2	The width of the footwear is alright.	84	16
3	The length is alright.	84	16
4	Comfortable with the top line.	86	14
5	The fastening aligned properly.	84	16
6	The depth of the Instep is alright.	92	08
7	No experience of new pain in any part of the feet.	95	05
8	The footwear is not too tight.	81	19
9	No experience of discomfort in any part of your feet.	81	19
10	Adjustment is not required in order to accommodate feet well.	76	24
11	No colour change was observed in any part of participants' feet after footwear was removed.	100	0
12	No swelling was observed in any part of patients' feet.	100	0
13	Blister was not observed in any part of the participants' feet	100	0

after footwear was removed.

Fit and comfort assessment of the prototypes presented in table 7.2 shows that up to 86% of those that participated in this research could wear the sandals easily. Over 80% reported that they were alright with the length and the width of the footwear. Similar percentage of the subjects also indicated that they were comfortable with the top line at the in-step. But it should be noted that up to 19% show that they experience some degree of discomfort when wearing the sandals. These were mainly patients that had swollen feet or some form of foot problems. Consequently, 24% reported that some form of adjustment to the footwear would be required in order to accommodate their feet well. Nonetheless, none of the patients observed or reported any new swollenness or blisters after the footwear was removed from the patients' feet. Similarly, the researcher could not observe any colour change in any part of participants' feet after the footwear was removed.

Table 7.4 Result of foot measurement and fit/comfort assessment.

Subjects	**Age (yrs)**	***Preferred Style**	**Foot Length Right (Left) (mm)**	**Foot Width Right (Left) (mm)**	**In-Step Girth Right (Left) (mm)**	****Fitting Assessment**		
						AA	**OK**	**UA**
P01	55	I	262 (262)	101 (102)	255 (246)		✓	
P02	63	I	265 (266)	108 (103)	261 (255)		✓	
P03	47	III	275 (270)	107 (107)	260 (266)		✓	
P04	47	III	290 (284)	104 (106)	265 (268)	✓	✓	
P05	70	I	286 (282)	117 (113)	275 (265)	✓		
P06	52	III	275 (271)	103 (108)	275 (248)		✓	
P07	58	I	286 (290)	112 (110)	282 (281)	✓		
P08	52	I	265 (268)	103 (98)	240 (240)		✓	
P09	75	II	264 (266)	89 (86)	230 (235)		✓	

P10	67	II	260 (257)	90 (92)	235 (229)		✓	
P11	30	III	274 (274)	83 (85)	230 (231)		✓	
P12	62	II	257 (256)	95 (96)	240 (235)		✓	
P13	76	III	257 (257)	91 (92)	236 (229)	✓		
P14	23	I	271 (270)	102 (108)	260 (253)		✓	
P15	23	II	257 (256)	93 (94)	241 (241)		✓	
P16	27	II	270 (267)	101 (95)	250 (254)		✓	
P17	DNM	III	265 (268)	92 (97)	260 (290)	✓		
P18	64	I	250 (246)	96 (96)	231 (225)		✓	
P19	80	I	265 (260)	107 (103)	262 (268)		✓	
P20	15	II	250 (248)	88 (84)	215 (220)		✓	
P21	48	II	265 (259)	101 (98)	270 (285)	✓		
P22	65	I	262 (260)	101 (10.1)	250 (260)		✓	
P23	DNM	II	255 (255)	96 (96)	235 (240)		✓	
P24	45	I	275 (280)	113 (106)	260 (265)		✓	
P25	54	I	264 (266)	106 (105)	260 (263)		✓	
P26	53	II	261 (267)	100 (100)	263 (260)		✓	
P27	53	III	271 (267)	100 (103)	286 (286)	✓		
P28	71	II	268 (269)	106 (107)	261 (260)		✓	
P29	45	I	271 (271)	107 (109)	285 (288)	✓		
P30	60	II	268 (264)	92 (93)	230 (230)		✓	
P31	75	I	260 (253)	104 (106)	258 (259)		✓	
P32	75	I	255 (255)	104 (100)	255 (2.0)		✓	
P33	50	III	260 (258)	96 (91)	245 (247)		✓	
P34	40	I	261 (265)	95 (97)	282 (283)	✓		
P35	45	I	255 (257)	95 (102)	245 (242)		✓	
P36	52	II	255 (248)	98 (96)	262 (260)		✓	
P37	40	I	258 (259)	85 (95)	258 (259)		✓	

***** Refer to fig. 7.13. ******Fitting Assessment was based on mainly: In-step fit, Length/ Width, whether sandals go onto feet easily or not, and whether the fastening aligned properly or not.

Key: DNM –Do not want to mention; **AA-** Acceptable but a little adjustment is required to accommodate feet well; **OK-** Fitting well; & **UA-** Unacceptable.

Table 7.4 gives more detail information of the subjects that were involved in the testing of the designed prototypes. The age, preferred style, foot length, width, In-step girth and remarks on fitting assessment of each participant are provided. Whereas 28 persons (that is 76%) reported that the sandals fit them well and were very much acceptable, 9 subjects (representing 24%) reported that the footwear were unacceptable in terms of fitting and that a little adjustment would be required to make the footwear comfortable for them. There was no single person that indicated that the footwear was unacceptable.

The researcher observed that those that reported that the footwear was tight or not fitting perfectly were patients that had swollen feet. In this case, participants P17 and P21 present a typical example were we have a difference of up to 30mm and 15mm between their right and left feet respectively.

The selection of the research participants at this stage of the work was biased in terms of gender and shoe size. It should be noted that only male patients and those who could comfortably wear normal size 42 (or 8) were involved in the testing of the prototypes. This is seen as a limitation of this project. A further study that would involve both genders and broad shoe sizes is therefore strongly recommended.

Some of the remarks made by the subjects on the footwear fitting (whether it was very tight, or very loose or fit perfectly) and the dimensions of their foot measurements were compared with the tolerable allowance for men (determined in the previous chapter). The calculated average tolerable allowance for male subjects was found to be 3.5mm. Therefore, looking at the dimensions of participants P17 and P21, particularly their In-step girth which was found to be 290mm (left foot) and 285mm (left foot) respectively, it can be confidently said that the dimensions of their feet are above the tolerable allowance. Table 7.1 shows that the circumference of the last (used to make the prototypes) at the in-step is 280mm. So when this is compared with the dimensions of the in-step girth of the above mentioned participants, we would notice that their foot dimensions exceeded the tolerable allowance with up to 6.5mm and 1.5mm for participant P17 and P21 respectively. This has given a clear proof that diabetic patients' feet must be measured correctly if they are to obtain footwear that fits well and maintains healthy feet.

7.6.3 Expert Assessment

In addition to testing of the prototypes with patients, the footwear were presented to medical doctors (mainly orthopaedic doctors and endocrinologists) at the Ahmadu Bello University Teaching Hospital, Zaria for critism and expert feedback. The doctors gave convincing statements that the prototypes will meet the needs of their patients, particularly those at risk of developing ulcers and other foot problems. They also mentioned, however, that those with deformed feet will require customised or bespoke footwear. One of the medical experts pointed out that "*footwear designed for diabetics is a welcomed technology. It will help in preventing foot injuries related to diabetes"*. Overall, a very positive feedback was received from the medical doctors about the designs, styles and materials used for the construction of the footwear.

Furthermore, footwear technologists' and designers' at Nigerian Institute of Leather and Science Technology, Zaria and industry base footwear technologists' views about the designs and construction were sought. The footwear experts expressed optimism that the products would meet the required parameters in terms of technical, aesthetic, comfort and fitting specifications.

7.7 Design Framework

A framework was developed as shown in figure 7.17 as a representation of the output of the research findings. The framework shows three step-by-step procedures for provision of appropriate footwear to people suffering with diabetes. The first step involves identifying individuals with diabetes and categorising them into patients with foot problems or at high risk of developing foot problems. The second level of the framework deals with assessing the specific footwear needs of the patient, and selection of suitable footwear materials/ components to make the appropriate footwear is done at the third level.

Regarding the implementation of the design framework, wide spectrums of professionals are considered to be key stakeholders. Nevertheless, the main stakeholders at the first level include endocrinologists, podiatrists and diabetic specialist nurse. These have the responsibility of identifying diabetic patients with an at risk foot or with foot problems like an ulcer. Immediately someone with foot problems or at risk of developing foot problems is identified, it is recommended that other stakeholders, mainly orthopaedic doctors, orthotists, and biomechanists should be involved at the second level of the framework. These professionals are expected to identify the nature of the patient's foot problem and the most appropriate type of footwear that could be recommended for the patient. For a very successful management of diabetic foot problems, it is advocated that a specialist in footwear materials, product developers, footwear designers and manufacturers should be given the opportunity to make their professional inputs at the 3rd level. To make the framework a complete cycle where there is a proper flow of information from one level to another, the product designed and made for the patient at the 3rd level should be sent to the specialists at the 1st level to check for proper fitting. If there is need for amendments, the professionals at the 2nd and 3rd levels should be involved accordingly. As noted in sub-section 8.9, referral of cases from one professional to another or the involvement of the appropriate stakeholders at the early stage in the management of diabetic patients would go a long way to reduce foot ulcerations and amputations.

Note that the PDS (refer to sub-section 7.5) is particularly linked to this design framework at the 3rd level. During the selection stage of footwear materials/ components, the product developer or manufacturer should refer to the PDS for the specific guidelines on appropriate footwear materials and ergonomic factors that must be taken into consideration during the design and manufacture of diabetic footwear.

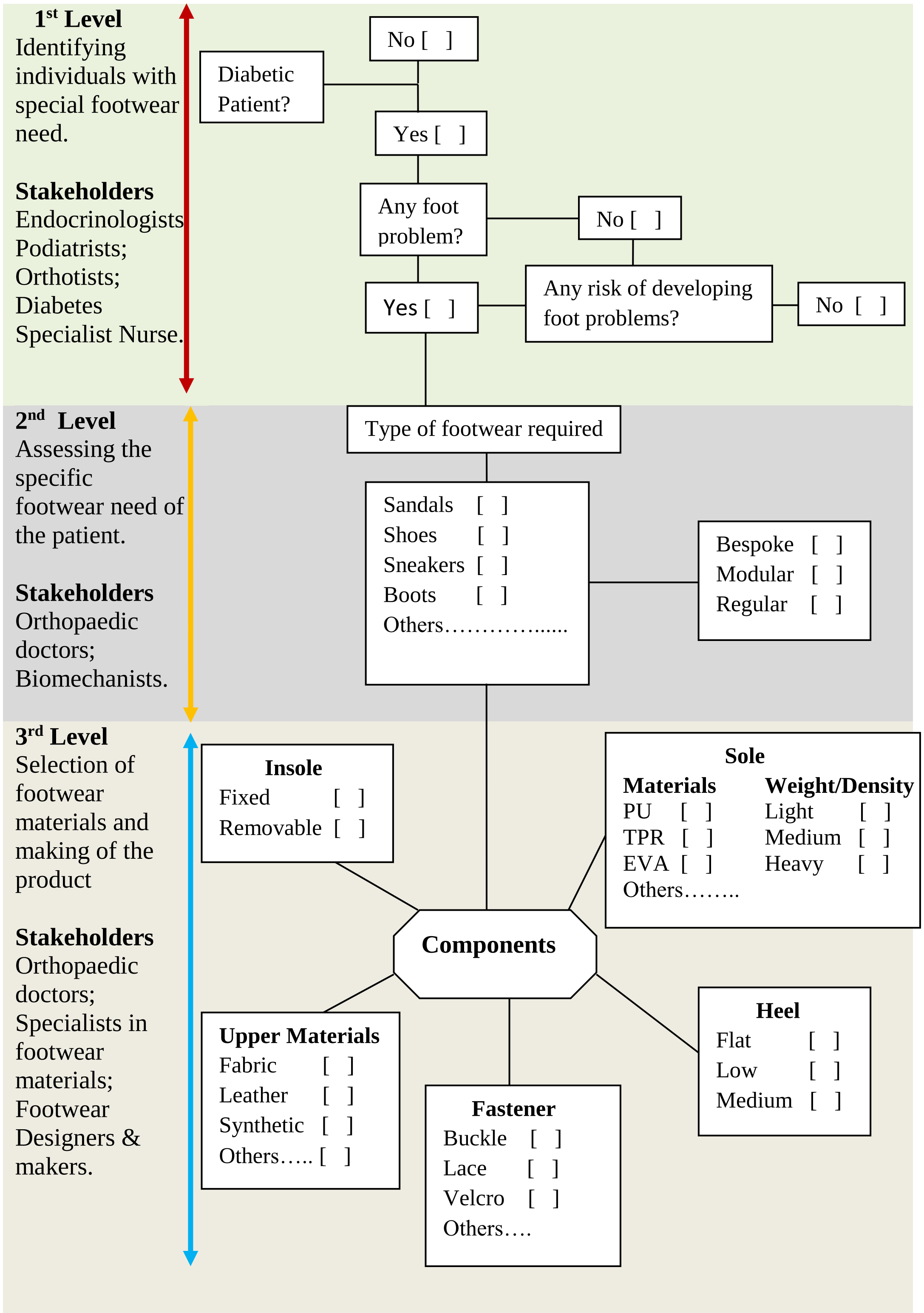


Fig. 7.17 Diabetic footwear design framework

As part of the strategy to solve the problems identified in this study, the author has developed a design framework (see fig. 7.17) for making appropriate footwear for diabetic patients. The concept consists of identification of persons suffering with diabetes by clinicians and categorising them according to their foot care need; (a) patients with foot problems, (b) patients at high risk of developing foot problems like ulcers, and (c) patients at low risk of developing foot problems. After assessing the foot care need of the patients by clinicians, it is recommended that patients with foot problems and those at high risk of developing foot problems should be referred to a foot care team (comprising different professionals including medical experts, designers, etc) who will investigate further about the foot care needs of each patient and give recommendations about the specific type of footwear and footwear materials for each case. From the survey, certain patients may require a special shoe last to be constructed to make the shoes in order to accommodate their deformed feet or to off-load areas of high pressure. The largest population of the patients would require footwear to be made on selected last but constructed with appropriate materials that will provide adequate protection and comfort for the patient's feet.

7.8.0 Discussion

7.8.1 The last

The last is a complex structure made from several measurements that are statistically determined. It has been described as "a physical object whose shape is an abstraction of the human foot" (Kühnert et al. 2011 P. 31). It is not indistinguishable to the human foot in shape or proportions. It is seen as a compromise of the two (Tyrrell & Carter 2009). In comparison to the human foot, the last girth, size intervals and dimensions are regular whereas those of the feet are irregular. In terms of substance, the human foot is softer and flexible while the last is hard and firm. The last is seen as the main element in footwear making and it constitutes the base for the footwear lasting process (Davia et al 2013). Therefore, lasts are used for both design and production of footwear and their shapes vary between footwear companies and are confidential due to the fact that they characterise the shoemaker's knowledge about a good fit of the footwear. For custom made footwear, a last must be made which represents an appropriate shape for footwear for the individual patient's feet. It is obvious that the need to have an individual last made for people with foot problems is one of the reasons for high costs of making bespoke footwear. Sometimes it becomes necessary that a small portion of a standard last is modified to accommodate certain foot conditions. Such modification would result in cost effectiveness when compared with making an entire bespoke last.

In this study, a standard or normal last was used (refer to fig. 7.2 & table 7.1) to design and make the prototypes. The feedback provided by the patients after the testing for fitting and comfort factors point to the fact that some parts of the last would require amendments in order to accommodate some foot deformities. In some cases a bespoke last would definitely need to be made. However, previous research (Davia et al 2013) has shown that there is a great challenge in the customised footwear manufacturing process due to the fact that it is difficult to apply specific models in the industry.

7.8.2 Trial Prototypes

This research resulted in making functional prototypes that were used to test various usability aspects of the product with prospective users. Footwear making is not as straightforward as many would think. It is described as "the art of producing a three-dimensional, dynamic article from a two-dimensional material; and pattern making requires the conversion of the round curves of the last into the flat upper components and then back into the curved shape of the shoe" (Tyrrell and Carter 2009. p. 33). The processes involved in the making of the prototypes and photographs of different stages in the making process are provided as appendix XVIII & XIX.

This research has revealed that sandals are well accepted among people suffering with diabetes in this part of the world. As can be observed from figure 7.6, sandals come in many different styles and designs. However, most sandals are basically the same. It has been shown that footwear style is not just a matter of design, but of foot comfort as well (Davia et al. 2013; Tyrrell & Carter 2009; Erasmus & Jorgensen 2008). For instance, some people cannot bear the feeling of a strap between their first and second toes. Still, some other individuals may have some type of foot deformity that would necessitate choosing one style of sandal over another.

Whereas a shoe will often put the foot under pressure by squeezing it, one of the advantages of wearing sandals is that they do not put the foot under pressure at all, and allow the foot to function normally (Erasmus & Jorgensen 2008; Nather et al. 2008). Therefore, sandals could be made not only to meet the aesthetic taste of the customer, but also to provide the desired foot comfort and to accommodate certain peculiarities or deformities in foot shape. As a matter of fact, sandals can easily be designed in such a manner that the possibilities of leather straps rubbing against tender spots or areas of high risk of developing ulcers are completely avoided.

The true aim of prototyping is not to show that the design is perfect or correct, but rather to reveal any feature that will affect quality, cost or consumer acceptance. Prototyping is also aimed at revealing mistakes, errors, and flaws prior to a release and mass production of a product. Therefore, prototyping is about revealing mistakes. According to Roosevelt (2010), “The only man who never makes mistake is the man who never does anything”.

In this study, it was noticed that real prototypes improved communication of the different features of the design compared with the printed version. For instance, the type of fastening used in the design of the sandals was better appreciated with the actual prototypes when compared with the response received with the printed version. This could be the reason for the wide variations in the preference of different fastenings between the initial survey (printed version) and the actual prototypes. A similar view is expressed by Chua (2010) on his write-up about the principles and application of rapid prototyping.

Apart from considering ventilation in the design of these prototypes, convenience and ease of use were also seen as factors that give a very wide acceptance of this type of footwear among people suffering with diabetes in Nigeria.

Previous studies (Chua 2010; Chang & Luh 2012) have shown that the use of a prototype as a communication device has many advantages, most especially when communicating ideas to those who do not understand or appreciate prints or CAD. In this study, the prototypes were made with materials used in actual manufacturing of the product. This was done deliberately to aid potential users to understand every aspect of the product, to feel it and to try it.

This work has proved that there is urgent need for collaboration across a number of disciplines including designers, engineers, clinicians, biomechanics, footwear technologists, etc to be fully involved to make footwear that could benefit a wide range of diabetic patients.

7.9 Chapter Summary

A brief description of the materials and methods used to make and test the prototypes was clearly given. A pair of last and various types of footwear materials were used to make the trial models and approved questionnaires were used to sample opinions on footwear designs and to assess the trial prototypes. Initially, 12 different footwear styles were designed and presented to potential users of the product and the top three selected were developed into functional prototypes.

Visual, fitting/ comfort assessment of the prototypes recorded high acceptability by the intended users of the product. In a similar way, feedback received from medical doctors and footwear designers/ technologies was very positive. The doctors' belief was that the product would be beneficial to diabetic patients if the prototypes are fully developed, produced and made available to the prospective users.

The information provided in this chapter demonstrates that development of appropriate footwear for people suffering with diabetes requires so many considerations including footwear style or design, fitting/ comfort factors, cultural and environmental issues. This study indicates that sandals are well accepted by potential users in Nigeria, especially in the Northern Region. The research showed that shoe size 42 or 8 is the most popular size for male subjects whereas size 40 is seen as the most widely used size among female subjects.

In summary, this research shows that people suffering with diabetes, especially those that are at risk for foot ulceration and who do not need custom shoes currently could benefit from this type (models) of footwear. The next chapter provides general discussions on the major outcome of the whole project.

Chapter 8: General Discussion

8.1 Introduction

No doubt, diabetes is associated with foot problems (Embil 2009; Levin & O'Neal 2008 & Bus 2008). However, data on the scale and nature of foot problems associated with the disease in developing countries are very poor. In addition, the level of awareness by patients and health care providers about the role of footwear in the management and/ or maintenance of foot health is very low. Therefore this study investigated how properly designed footwear could be used to better manage diabetic foot problems because footwear is seen as a health intervention tool (William 2008; & Katreddy et al 2010). It also examined footwear materials in respect to foot health, the dimensions of shoe last and dimensions of the foot. Lastly, prototypes were made and used to test usability of the product from prospective users.

The findings from this research are seen as very important because to the knowledge of the researcher, a study in this subject area has not been undertaken in Nigeria. Following is a discussion of the major outcome of this study. The significance and importance of the project are also outlined in this chapter.

8.2 Research Methodology and Data Analysis

1. Research Methodology

The choice of the type of research methodology adopted for this study was largely informed by the research aim/ objectives, the expected outcome and the time frame. It was discovered that the nature of the research demanded a methodological approach that embraces both qualitative and quantitative data collection. Crouch & Pearce (2012) strongly advocated for this type of research methodology for any study that needs to generate research findings that can be generalized across a large population and at the same time to understand in some depth the individual experiences of a small group of people.

The questionnaire survey (refer to chapter 3) used for collecting information from diabetic patients was chosen because it was anticipated that it would provide data from a sizeable number of patients that could be used for making inferences for the whole diabetic population in Nigeria. At the same time, the researcher used a structured questionnaire to interview the medical doctors bearing in mind that such an approach would provide him with the required information within the research time scheduled. A non-structural interview method that requires more time to gather information and analyzed could not be used. Nonetheless, open-ended types of questions were included in the structured interview questionnaire in order to allow the interviewees to describe or explain their experience of particular issues in more detail (see appendices IV & V). Also, to complement the findings gathered through the questionnaire and interview surveys, two additional studies (footwear materials analysis and foot measurement) were designed. The footwear experimental analysis provided valuable information regarding the physical and mechanical properties of shoe upper materials that could influence the comfort of diabetic footwear. The results of the foot measurement were very useful in determining footwear fitting features mainly during the assessment of the trial prototypes.

This mix-methods approach enabled the researcher to use some of the methods or aspects of the methods to identify the key issues whereas other aspects or methods provided detailed information on some of the issues raised. In addition, some of the methods complement the findings of other methods.

For effective data gathering and understanding of the researcher methods adopted, the researcher carried out a thorough literature review throughout the period of the study. The data gathered both from the primary and secondary research were used to develop PDS, design framework and functional prototypes. The prototypes were evaluated and the findings from all aspects of the study were discussed. Finally, the implications of the research work, conclusion and recommendations for further research were identified and outlined.

2. Data analysis

There are many approaches to analyze research data. Qualitative data concerns the interpretation of text. Quantitative research involves working with numbers and using statistical analysis.

Crouch & Pearce (2012) proposed that any researcher work which use questionnaires as a form of data collection may not need to go beyond the use of descriptive statistics and the exploration of the interrelationships between pairs of variables (using for example, cross tabulation). It would be adequate to say that so many responded (either the number or the proportion of the total) answered given questions in a certain way. Such an analysis makes wide use of proportions and percentages, and of the various measures of central tendency (averages) and dispersion (ranges). In order to ensure that the right approach to the analysis of the data collected in this study was employed, the researcher first consulted professionals in statistical analysis at Kimberlin Library in DMU.

The analysis of the outcomes from interviews, questionnaire surveys and foot measurements was carried out systematically, first through thematic analysis, followed by computing the data using Microsoft Word 2007 and Excel 2007 to represent the outcomes in the form of bar and pie charts and tables. However, the results from the experimental analysis were done mainly by using formulae and representing the results in tabular forms.

The data from different methods used were analyzed, re-arranged and represented to show low and high values. The represented values were observed for certain patterns so that comparative analysis could be done, for example type of footwear worn most often by male versus female.

8.3 Diabetes

The current global epidemic of diabetes (type 2 in particular) has led to an increase in both foot ulceration and amputations, which are regarded as significant health problems to populations worldwide. It has been established (Bakker 2011; White 2010) that people with diabetes experience foot ulcers, swollen feet and different types of foot deformations. The literature clearly indicates that 50% to 80% of all amputations are diabetes-related, and the majority of these amputations are preceded by ulcers (Bakker 2011; White 2010; Boulton et al. 2005). In addition, a cross-sectional hospital-based study conducted by Unachukwu and his colleagues (2006) in Port Harcourt, Nigeria shows 38.1% prevalence of diabetes mellitus among medical inpatients, while foot ulcers was 19.1% among diabetic patients.

Mbanya et al (2006) argues that despite some local data, the burden of diabetes in Africa is difficult to estimate. Accordingly, the findings from this study (from diabetic patients' respondents) shows that at least 67% did not know the type of diabetes they were suffering with. Nonetheless, 28% reported that they were suffering with type 2 diabetes and only 5% indicated that they have type 1 diabetes. And from the viewpoint of the medical doctors interviewed, up to 93% of their patients could be suffering with type 2 of the disease, whereas at least 7% might be suffering with type 1. The findings from the doctors confirmed a previous publication (Beran & Yudkin, 2006) that state that type 2 diabetes in Africa is rising in epidemic proportions. The data from this project has therefore contributed to the required information on diabetes from the most populous nation in Africa (Nigeria).

8.4 Foot problems and footwear.

Foot problems are seen as the major complication of diabetes (National Diabetes Fact Sheets 2011; Vernon 2007). The literature (Krentz & Bailey 2001; World Footwear 2008; Johnson & Rogers, 2011) points out that people suffering with diabetes could easily develop foot problems because of how easily nerve damage can occur there without immediate detection. This usually leads to loss of blood flow, and subsequently numbness to the extremities. Consequently, infections may go entirely unnoticed until it spreads beyond repair. This condition can also have a significant effect on wound healing and management (White 2010). Therefore, it is advisable that people with diabetes should be more vigilant to prevent injuries that are more likely to damage their feet (Kennedy 2010; World Footwear 2006). Results on the nature and scale of diabetic foot problems were presented in chapters 3 and 4. The results show that up to 40% of research respondents were suffering with foot problems. This is in complete agreement with previous publications (Abbas & Archibald 2007; Beran & Yudkin 2006) that indicate that the prevalence rates of the disease in Africa are increasing and foot complications are rising in parallel.

A recent study (Stimpert, 2014) on customized footwear points out that people in the developed world with foot issues or health problems now have a wide array of options in customized footwear, more than ever before. Nonetheless, this study shows that such options have not be made available to people who need custom shoes in Nigeria.

It has been explained that footwear can have a negative or positive influence on the diabetic foot depending on whether the footwear is appropriate for the wearer or not (Vernon, 2007). Also, researchers (Munro & Steele 1998; Haspel 2007; Wright 2010; Jude 2011) continue to argue that diabetic foot complications could be prevented and/ or minimized with early diagnosis of diabetes, good patient education, effective treatment and the use of quality footwear to off-load areas of the feet which have ulcerated or potentially will ulcerate. Other authors (Przybylski 2010; Ulbrecht & Cavanagh 2010; Ivy et al. 2008; Boulton 2008; Knowles & Boulton 1996) point out that diabetic foot problems incur a substantial economic burden for society, patients and families globally. The work of Nathan and Singh (2008) on "Diabetic footwear: Current status and future directions" indicates that shoe-related injuries are the major cause of diabetic foot problems. However, they show that the prescription of diabetic footwear leads to a reduction in new foot ulceration and as a result, a reduction in lower extremity amputation rates. Similarly, information gathered from both diabetic patients and the medical doctors in this study clearly indicates that inappropriate or ill-fitting footwear has a negative influence on the diabetic foot. While the research outcome of Ulbrecht & Cavanagh (2010) shows that up to 37% of diabetic patients wear ill-fitting shoes that result in foot ulcerations, even in the non-diabetic patients, 24% wear shoes in the wrong shoe size. This present work provides data that point out that urgent intervention is required to stop or at least reduce the rate of foot complications as a result of wearing inappropriate footwear.

The findings from the questionnaire survey (refer to chapter 3) give evidence that the majority of diabetic patients in Nigeria lack knowledge about foot care and use ‘bad’ footwear that could contribute to the most devastating, preventable foot complications. The author argues that poor knowledge of diabetic foot complications and lack of knowledge on how to manage the disease are among the major reasons for the high percentage of diabetic patients experiencing foot complications in this part of the world. Contrarily, there are well-established research teams in Europe and America that conduct studies on diabetes, its complications, and how to solve such problems. For instance, the European Union gives special attention to solving the problems of diabetic foot problems by sponsoring a research project (SSHOES Project) to design and develop new sustainable product concepts, such as footwear and insoles for diabetic feet (S-Shoes, 2012). It is therefore recommended that similar projects should be initiated in Nigeria and other African countries.

In order to relate the doctors’ views and the patients’ experience on the most widely used footwear type, a comparison is made between the results obtained from the interview and the questionnaire surveys (see table 8.1). The views on the type of footwear most widely used by diabetic patients in Nigeria from the perspective of the doctors and the patients were found to be consistent all through. Looking at the table, both surveys show clearly that sandals are the most popular type of footwear used by male patients, while slippers are seen as the most widely used footwear by the female patients. This further justifies the choice of sandals for making the trial prototypes. From the results of this research it can be concluded that the concept of utilizing footwear to protect the foot from injury, the factors that go into establishing patient’s footwear needs and footwear modifications are seriously lacking among patients and health providers in Nigeria. It is believed that this project will go a long way in creating awareness about the many roles footwear can play in the management of diabetic foot problems.

Table 8.1 Comparison of the outcome of the interview and questionnaire surveys in respect to type of footwear most often used by diabetic patients**.**

	Gender	**Shoes (%)**	**Half Shoes (%)**	**Sandals (%)**	**Boots (%)**	**Slippers (%)**	**Sneakers (%)**	**Custom Made (%)**
Findings from the doctors	Male	15	17	35	05	26	01	01
	Female	11	18	25	00	45	00	01
Findings from the patients	Male	17	14	29	01	37	02	00
	Female	13	15	19	00	53	00	00

8.5 Product Design Specification (PDS) and Design Framework.

In general terms, design is essentially a rational, logical, sequential process intended to solve problems (Novak-Marcincin 2012; Jimeno-Morenilla & Davia 2010;). The process of this work began with the identification and analysis of diabetic footwear needs and proceeded through a structured sequence in which relevant literature was researched and ideas explored and evaluated until a solution to the need was proposed. Specifically, this project investigates acceptable footwear that could benefit people suffering with diabetics in Nigeria. This was done by studying a range of factors that could determine the design and appropriateness of footwear for diabetic foot through the formulation of a Product Design Specification (PDS). The PDS was useful in the selection of materials and designs for the prototypes. The key elements that must be considered in the design and selection of materials for diabetic footwear include comfort and ergonomics, environment, etc (see chapter 7, sub-section 7.5).

Based on this study, a close relationship between the PDS and the research framework, particularly at the third level (i.e selection of footwear materials and components), can be observed (see previous chapter, sub-section 7.8). The framework provides a concept which consists of identification of persons suffering with diabetes by clinicians, categorising them according to their foot care needs and recommendations about the specific type of footwear and footwear materials for each case. It is believed that clinicians and product developers can confidently use these tools to develop appropriate footwear for individual patients. This is considered as a very important contribution of this project in the subject area.

This work further shows how it is difficult to give a generalized specification for diabetic foot as the shape of the feet may differ significantly one from another due to different foot problems some of them experience. However, a number of functional requirements or necessities affect the structure or type of diabetic footwear. These functional necessities add to the complication of the designer’s task in designing the most appropriate footwear, and give the designer the necessary elements out of which he can produce the variety of his footwear styles and shapes. Therefore in an attempt to meet the design requirements of diabetic footwear, the author discovered from the data obtained from both the primary and secondary research that functional requirements or need of the diabetic foot should come first, and then structure requirements, and finally requirements of aesthetic appearance (Covington 2009; Harvey 1992).

8.6 Last and Foot Dimensions.

Different views of the last that was used to design and make the prototypes and its dimensions are given in this thesis as figure 7.2 and table 7.1 respectively. It has been pointed out that the last is the main element in footwear design and it constitutes the base for the footwear lasting process (Davia, et al 2013). In chapter 7, it was demonstrated that to make suitable footwear for diabetic feet, an appropriate last must be made which represents an appropriate shape for required footwear for the individual patient’s feet.

In regards to the dimensions of the foot, it is generally noted that the outcome of the right and left foot measurement of most individuals differ one from another. Similarly, the results of the foot dimensions of those wearing the same shoe size varies one from another. These findings are in complete agreement with the research outcome of some studies (Pezza 2011 & Sandrey, et al. 1996) that note that it is rare to find a diabetic patient who is wearing the proper shoe size. Similarly, this research shows that the differences in foot dimensions (length) for subjects wearing the same shoe size could be up to 21mm (refer to subject M_B19 and M_B15 in table 6.2). In like manner, a difference of at least 20mm in foot width was recorded between subjects M_A06 and M_A11. Appreciable differences could also exist at the in-step of individuals wearing the same shoe size. It is therefore argued that these differences could become a source of major discomfort for the subjects when wearing footwear when such differences were not taken into account. Generally, it is observed that the differences in some people's foot length, width and in-step can be negligible whereas some could have appreciable variations.

8.7 Trial prototypes: Why Sandals?

The need to design appropriate footwear to diabetic patients' satisfaction has been noted in the introduction (sub-section 1.3). It was also pointed out that most of the studies on diabetic and orthopaedic footwear were mostly based on clinical need and perspective, without an in-depth understanding of patients' expectations and perceptions of footwear. The literature has shown that two thirds (2/3) of diabetic patients wear poor-fitting footwear, but that shoes designed for people suffering with diabetes could reduce re-ulceration rates by half (Leese 2009). For this research, trial prototypes were developed after a careful study of the problems from previous works, from the viewpoint of medical doctors and from the perspectives of diabetic patients.

Tyrrell & Carter (2009); Nathan and Singh (2008) pointed out that shoes, sneakers and bespoke footwear are the recommended types of footwear for at risk foot. However, financial constraints or limited economic resources force most people suffering with diabetes in Nigeria to use cheap footwear regardless of whether they provide the desired protection and comfort to them or not. For many patients (see sub section 3.7.7), price rather than quality is the major concern when buying footwear. The majority of the population lives in poverty and faces economic challenges. In view of the above factors, sandals were considered as the most appropriate type of footwear to be developed as the prototypes. In addition, Sandals became the best choice on the basis that the are popular and that a well-designed sandal, constructed with appropriate materials would provide the desired protection and comfort to the wearer which is affordable. This is because the cost of making a pair of sandal usually is not as high as shoes or sneakers. Another good point for choosing this type of footwear is due to the fact that they could provide enough room to comfortably fit swollen feet. Also, the rate of feet perspiration in this part of the world could be very high (refer to table 7.2) and the use of sandals are considered very appropriate as they provide good ventilation.

Clearly, there was a mismatch between the types of footwear desired (leather shoes) and the type of footwear that are available and affordable. Different kinds of slippers are the most prevalent types of footwear used among the patients. These are cheap and widely available in the local markets. Although they are accessible, they are considered as inappropriate for diabetic patients because they do not provide good protection and due to the fact that low-quality materials are used to make them, and they may be uncomfortable.

Therefore, after a careful survey on the most preferred and appropriate footwear for diabetic patients in Nigeria, three basic types of footwear (sandals) were produced and used to assess the acceptability of the products from prospective users. The idea behind the three designs (see fig.7.13) was to provide footwear that would give good instep support to the foot whereby preventing the foot from sliding forward to exert pressure on the metatarsal head of the foot. Other features critically considered in the design of the prototypes were comfort, ventilation and lightness of the footwear. This is in line with the general guidelines for provision of healthy footwear for diabetic foot (Steed, et al. 2008; Bus, et al. 2008; Vernon, et al. 2007; Lobmann, et al. 2001).

The outcome of the assessment of the prototypes presented in chapter 7 clearly shows that the products are well accepted by both patients and medical doctors. The products are therefore recommended for all diabetic patients that do not have a major foot deformity and for people who may find it very difficult to use lace or buckle shoes. They can equally be used by middle age and old people whose feet may or may not be at high-risk of developing ulcers.

8.8 Footwear materials and components.

1. Upper materials

The upper part of the footwear (see fig.8.1) comprises of the counter (the part of the shoe extending around the heel), toe box (the part that covers the toe area), vamp (the part that covers the instep), and throat (the part at the bottom of the laces). Leather is seen as the most used natural material for footwear upper because of its versatile properties of plasticity and elasticity and other ideal characteristics for footwear (Bata 3013; Tyrrell & Carter 2009). Leather is soft, it breathes, offers very good absorption ability and is able to adjust to an individual’s foot shape.

The result of the analysis of footwear materials presented in chapter 5 demonstrates that leather has good comfort and strength properties. For instance, the breathability of the samples determined using the water vapour permeability test indicates that diabetic footwear upper should be made with leather because it has properties of particular value in terms of foot health. It has excellent ability to allow air and water vapour to pass through the cross section of the upper. Other materials like coated fabrics and poromerics have excellent properties in respect to water repellency and resistance. However, they have poor water vapour permeability property, hence poor breathability (Harvey 1992; Jone 2000).

It was learnt from the interview survey that the majority of doctors would prefer footwear made for their clients to be constructed with leather (refer to fig.4.11). Similarly, the patients are of the view that leather is the best material for shoe upper (see fig.3.14) Furthermore, the following are particularly noted in regards to the construction of the footwear upper after a review of the literature and the primary research: The upper should be designed with no interior or minimal seams (or covered seams) to prevent rubbing injuries; the seams can be used only where the shoe does not flex; the design should give room for easy adjustment to fit, to prevent the diabetic shoe from sliding around on the feet; appropriate fastener must be used for the upper.

Fig.8.1 Parts of a shoe. Available from:
http://gluxus.com/wpcontent/uploads/2013/07/parts-of-shoe.jpg

2. Insole

Even though the experimental analysis of the footwear materials mainly focused on shoe upper; the secondary research shows that insoles provide the important interface between the foot and the shoe and, together with outsole modifications, offer the most direct approach to the reduction of potentially damaging tissue and stresses on the plantar part of the foot. And in respect to insole functions in reducing local peak pressures, research has shown that contoured insoles are significantly better than flat insoles (Bonnie et al. 2004).

Research has shown that there are a great variety of insoles materials available for shoe designers to use, but for diabetic footwear construction, multi-density EVA or PU are recommended (Tyrrell & Carter 2009). This is because they can easily be moulded and trimmed to the desired foot shape. Very soft PU or EVA materials are found to have good cushioning property; hence they are very suitable for making footwear for those suffering with diabetes or people that need to offload high pressures from the metatarsal heads (MTHs) and other areas.

4. Sole and Heel

Again, the literature (Cavanagh & Ulbreacht 2008; Rahman 2003) clearly shows that the most common sole suitable for diabetic foot is the rigid rocker-bottom shoe or a variant thereof called a roller. The rocker has a break in the contour of the sole, whereas the roller has a smooth curve. The principle for designing the diabetes shoe out-soles is to allow the patient to walk with minimum motion of the joints of the foot. The following are the desired elements of out-sole and heel in regards to diabetic footwear.

- Firmed and resilient
- The top of the sole should be soft and hard at the bottom
- Should be made with two components (dual density)
- To reduce pressure on the metatarsal head, medium to low heel should be used.

In summary, to design or make good and acceptable footwear for people living with diabetes, the points given below must be critically considered:

- Diabetic footwear should be seamless or have less seam at positions where the shoe does not flex.
- The shoe should be wide because some patients can have claw toes.
- The shoe should be deep enough to accommodate insert insoles that can be replaced regularly.
- The upper should be soft and breathable.
- Medium to low or flat heel should be used in the design and construction of diabetic footwear.
- Dual density sole should be used.
- The insole must be soft and should have good pressure distribution properties.
- Proper fastening (using Velcro or laces) is very important.
- The design should be fashionable, socially and culturally acceptable by the patients. Design that may imply or encourage stigmatization must be avoided.
- The shoes should be made with environmentally friendly materials.
- The design size should be available in different widths to allow for proper accommodation of wider feet.
- The appropriate materials, for example soft leather for the upper should be used for making the shoes.

8.9 The need for a multidisciplinary approach.

It was stated in chapter 1 that the management of diabetic foot complications needs a multidisciplinary approach because diabetic foot problems are multifaceted. The role played by such teams in regards to foot care have proven to decrease amputation rates among diabetics and increase their satisfaction with footwear. Therefore, practitioners treating people with diabetes advocate that each team member must understand the principles and practice of comprehensive foot care, including the prescription of appropriate footwear (Mclnnes 2011; Tyrrell & Carter 2009; Noble-Bell & Forbes 2008). In this study, doctors involved in the treatment of diabetic foot complications also expressed the need for active involvement of all professional members in the early stage of the treatment in order to improve results. A point to note on this issue is the unfortunate situation that the multidisciplinary approach to addressing diabetic foot problems is yet to be understood and practiced in Nigeria. To make the point clear, a comment made by an orthopaedic doctor during the interview survey is given thus:

> *Diabetic foot ulcers/ sepsis is the common cause of non-traumatic cause of amputation of human limbs worldwide and Nigeria has a great burden of diabetic mellitus. There is paucity of multidisciplinary approach to diabetics with orthopaedics being the least consulted until very late in the management. Thus there is need for early referral to orthopaedics and the need for orthopaedic surgeon to rise to the challenge to prevent this depressive event and not just to amputate a limb.*

In summary, the multidisciplinary foot care team is seen as the most effective way to provide patient education and to manage foot problems (Ellis, et al. 2010; Nather et al. 2010).

8.10 The need for education and awareness.

With increased awareness of the role of footwear in the prevention and management of diabetic foot problems along with expertise in the design of appropriate footwear, it is believed that the high rate of amputation reported amongst diabetic patients would be drastically reduced.

Whereas probably the most important area to research in the developed world would be usability of diabetic footwear; in the developing world, the problem is first and foremost the matter of awareness and education about diabetic foot complications and the role of footwear in the management of foot problems or for the maintenance of good foot health.

Doctors that participated in this research pointed out that health practitioners involved in the treatment of diabetic patients would need further and continued education of the role footwear plays in the management of diabetic foot problems and/or prescription of diabetic footwear. They further state that information and education on footwear should be introduced in health care centres (refer to chapter 4, sub-section 4.8).

8.11 Cost consideration

The study of chapter 3 suggests that the current situation in Nigeria in regards to provision of appropriate footwear for diabetic patients is not that the best shoemaker cannot provide a very good solution for individuals with foot problems; but it is difficult to make quality or standard footwear for the vast majority of patients at a realistic cost. Even though the majority of diabetic patients would be willing to use orthopaedic footwear, a greater percentage of them would not be able to afford prescriptive footwear that could cost double the amount they use to buy footwear (refer to sub-section 3.7.7). And based on the cost implications of the sandals made for this project (turn to chapter 7), the approximate cost for producing the footwear is found to be ten thousand naira (₦10,000.00) or forty pounds (£40.00). Considering the outcome of the survey in chapter 3 in respect to the amount the patients would be willing to spend on a pair of prescriptive footwear, the majority would not be able to afford the product even at that rate. The result of the study (see fig. 3.17) shows that only 9% and 3% of male and female subjects respectively would be willing to spend up to six thousand (₦6000.00) or twenty four pounds (£24.00) on a pair of diabetic footwear.

This is seen as a very challenging situation. Therefore for proper diabetic foot care in Nigeria, the author advocates for involvement of government and non-governmental organizations in the provision of prescriptive footwear to people suffering with diabetes by supplying appropriate footwear free of charge or at a subsidised rate.

8.12 Significance and Implication of the Project.

Through this study, current and relevant data on a wide range of issues regarding diabetic footwear have been obtained and documented. The outcome of the research will be helpful to designers, manufacturers of prescriptive footwear, the academics, etc to design appropriate footwear for diabetic patients and to educate the diabetic population on the role of footwear in the management of their foot problems.

The findings have shown that an appreciable percentage of people living with diabetes have foot problems. The number of those suffering with foot problems in this part of the world is particularly high when compared with the result of similar surveys conducted in the UK (Tagang 2010). This can be linked to a low level of awareness of how to manage their foot problems using correct footwear in addition to the medical care. It was also discovered that many diabetic patients are wearing inappropriate footwear that could cause or complicate their foot problems, as it has been shown that ill-fitting footwear can actually cause foot problems (Cavanagh 2008; Vernon 2007 & Edmond & Foster 2005). This implies that urgent action must be taken to improve the lives of those affected with diabetes in Nigeria by providing them with shoes that fit because it has been pointed out in the literature review (Levin & O’Neal 2008; Bus 2008; Jeffcoate et al. 2008) that appropriate footwear improves the standard of living for diabetic patients.

Dimensions of the left and right feet of some individuals can slightly differ in length and width. In this study, it has been demonstrated (see sub-section 6.5) that the foot morphology can differ significantly from one individual to another. It is therefore concluded that proper foot measurement and footwear fitting is required for effective treatment of diabetic foot problems. In addition, treatment should focus on prevention as well as treatment with suitable materials including footwear that is culturally appropriate and adapted to populations with poor incomes since the majority of the population in this region is classed as low-income earners. One important approach to achieve this, Olivato (et al. 2007) recommended that designers and manufacturers should understand individual personal foot characteristics when designing and making footwear for people with foot problems or at risk of developing foot problems.

Based on the Shoe and Allied Trade Research Association (SATRA) Standards for water vapour permeability and related tests, the shoe upper materials analysed have revealed that leather has good breathability properties required for diabetic footwear manufacture. This shows that leather allows water vapour (or perspiration from the foot) to pass through. This is very important in determining the comfort of a shoe and indicates that the materials that should be used to make diabetic footwear must be carefully selected. In addition, suitable materials that are culturally appropriate to populations with poor incomes or low-income earners must be considered for making footwear for people suffering with diabetes in this region.

Finally, the study provided areas for further studies which if properly investigated could provide better footwear materials and design solutions and/ or options for people living with diabetes.

8.13 Chapter Summary

In this chapter, the author gives a general discussion on the main findings and an overview of the significance and implications of the research. The discussion points to the fact that footwear can play many roles including foot protection, comfort and improving foot health. To make appropriate footwear available to diabetic patients in Nigeria, there is an urgent need for a joint effort by professional groups (e.g health care providers, designers, industrialists, etc.), government, non-governmental organizations and an active participation of people suffering with diabetes.

The conclusion and recommendations for further studies of this study are stated in the next chapter.

Chapter 9: Conclusion and recommendations

9.1 Introduction

This thesis is divided into nine major chapters. A summary of each chapter has been given but this last chapter summed up the entire work. Conclusions based on the research objectives are outlined followed by the shortcomings of the project. Other important issues pointed out in this chapter are; the contribution the work has made to knowledge, collaborations entered into during the course of the research, reflections from the research and recommendations for further studies.

9.2 Meeting the research objectives.

1. To search and review the relevant literature regarding the subject area.

Following a review of the literature associated with this subject area, it was discovered that inappropriate footwear can cause or complicate foot problems, especially among diabetic patients. Interestingly, the literature also revealed that appropriate footwear plays an important role in the management of the diabetic foot (Ulbrecht & Cavanagh 2010; Mara 2011; Edmonds & Foster 2005). The review of the literature shows that there are quite a number of footwear styles that have been developed in developed societies that are aimed at meeting the specific needs of the diabetic foot. However, there is a persistent problem of patient dissatisfaction and low usage of diabetic footwear in developed societies (Williams & Meacher, 2001), and the need for a multidisciplinary approach to solving the problem has been identified.

Data obtained from previous research reveals a different problem of the issue in developing societies (particularly of Africa). It was discovered from the literature that information on diabetes, foot problems, and the use of appropriate footwear in Africa is very poor (Tagang 2010; Mbanya 2006). Secondly, there is the problem of education or awareness of the role of footwear in the management of diabetic foot problems. Thirdly, the provision of required services (including a multidisciplinary approach to solving the problem) and the product are lacking (Abbas and Archibald 2007).

Consequently, this study has discovered major gaps in the literature in respect to data on diabetes and diabetic foot problems, appropriate designs for diabetic foot, technical requirements for diabetic footwear materials and appropriate last for designing and making of footwear for diabetic patients. Thus in summary, the present work was an attempt to provide data that would meet at least some aspects of the identified gaps in the literature.

2. To source for relevant information from diabetic patients using a questionnaire survey.

To achieve this very important objective, a questionnaire was designed for the study and a total of 156 questionnaires were correctly filled in by diabetic patients in Nigeria, returned and analysed. For the validation of the questionnaire, a pilot study was first and foremost carried out to obtain professional feedback about the initial version of the survey materials, to collect preliminary information from the proposed research participants, to identify ways to improve the survey items and to identify ways to administer the actual survey to participants effectively.

In this study, it was discovered that up to 67% of the participants did not know the type of diabetes they were suffering with and up to 40% of the patients were suffering with foot problems like pains, ulcers, blisters, wounds, etc. In addition, up to 75% of the diabetic subjects that participated in this study reported that they had not received information about the type of footwear they should wear most often. Therefore, this thesis has made very clear the need for health care providers to become very proactive in designing awareness programmes that could provide patients with information about diabetes and the different types of the disease.

Another important finding of this study is the nature or type of footwear worn by diabetic patients in this part of the world. Our data reveal a very poor choice of footwear by people suffering with diabetes. It was discovered that majority of the patients were wearing slippers most often. In regards to footwear fitting, the outcome of this study shows that at least 29% of the subjects found it very difficult to put on or take off shoes and 31% agreed that their footwear needed modification in order to accommodate their feet well. Also, a greater percentage of them do not have access to practitioners trained in fitting footwear for diabetic foot.

3. To source for information from health professionals on the important factors to be considered for designing diabetic footwear.

In this study, a structured interview questionnaire was used to collect information on the research areas from forty-five medical doctors with varying years of experience. The mean years of experience of the respondents was found to be 10.2. The interview provided insight into medical opinions about the issues. Again, a pilot survey was carried out which provided valuable information that was used to plan and conduct the main survey successfully.

The findings from the medical doctors revealed that at least 32% of diabetic patients could be suffering with foot problems in this part of the world. According to the respondents, the majority (82%) of diabetic foot problems could be related or linked to wearing ill-fitting or inappropriate footwear that contributes significantly to the susceptibility of the diabetic foot to injury and infection. The survey further revealed that a large proportion (68%) of the doctors indicated that regular shoes are unable to accommodate the feet of their patients due to one type of foot problem or another. Even though custom-made footwear (e.g orthopaedic shoes) are seen as an appropriate footwear that could be prescribed to a wide variety of patients to diminish or prevent foot problems (Netten et al. 2010), unfortunately, in this study it was discovered that custom-made footwear are not being prescribed to sufferers of diabetes in the country, even those with foot problems.

The overall score of knowledge of medical doctors in this part of the world on foot care and provision of special footwear like orthopaedic/ diabetic footwear was found to be very low. The medical experts also pointed out that many clinicians have overlooked the importance of footwear in the management of diabetes and they believe that this work will create more awareness among health care providers and patients on the subject matter. These findings did not differ significantly in comparison with previous studies (Frykberg 2006; Abbas & Archibald 2007) that revealed lack of knowledge of foot care among patients and health care providers in Africa and other less developed countries, leading to further foot complications.

In addition, it was discovered that the majority (up to 66%) of the patients may be wearing footwear that do not have any form of fastening. That is, most of them are using slip-on or slippers (with no fastening mechanism) most often. It is really regrettable to observe that footwear with important fastening features like lace, buckle or velcro are the type of footwear least-used by diabetic patients in the country. Therefore, it is argued that footwear available in the Nigerian markets is not meeting foot health requirements of diabetic patients.

It is concluded that to change the dreadful situation of diabetic foot complications, identification of a foot problem by clinicians must be followed by appropriate treatments including prescription of appropriate footwear. Also, to help patients make informed choices of self-care, particularly in relation to footwear, health care providers should always give diabetic patients relevant information and assistance on how to recognize footwear broadly suitable to the maintenance or improvement of foot health and the type of footwear that should be avoided as being potentially detrimental. It is also very important that healthcare professionals support and stimulate research in establishing diabetic footwear programmes in the country.

4. To study appropriate footwear materials for making diabetic footwear.

The experimental analysis of footwear materials gives a glimpse into the physical properties of the material widely used for footwear manufacture. Tests were undertaken on key parameters like water vapour permeability/absorption and water absorption, tensile strength, apparent density etc, to determine and assess comfort and strength properties of shoe upper leather samples. These tests have been shown as the most frequently used experiments to measure the comfort and strength properties of shoe upper leathers (Covington 2009; Wilson 2000; Bata 2013).

This study demonstrates that a careful selection of materials based on their comfort and performance properties have far-reaching benefits in terms of foot health. It has been stressed that leather is the most used natural material for footwear manufacture because it presents ideal characteristics for footwear (Bata 2013). This study has further proven that leather has properties of particular value in respect to foot health. Generally, the results obtained were found to be similar to the outcomes of previous studies and in conformity to set standards. In summary, the experiments indicate that a thorough knowledge of the physical properties of footwear materials would lead to identification of suitable materials that could improve foot comfort and safety to the wearer.

5. To develop appropriate footwear design(s) solutions for people living with diabetes, particularly in Nigeria.

To meet this objective, a number of studies were carried out including determination of last and foot dimensions, development of product design specification, making and assessment of trial prototypes and development of a research framework.

280 normal adult volunteers were involved in the study of foot dimensions. Of this number, 186 (66%) were male and 94 (34%) female. The basic foot dimensions (that is length, joint girth or width and in-step) used by clinicians to determine the type of footwear needed to meet the patient's requirements were measured, recorded and analysed. In order to understand if the prototypes would fit the user well or not, the measured values were compared with the last dimension and the tolerable allowance (which was found to be 3.4mm and 3.5mm for male and female subjects respectively). The outcome indicates that no individual's feet are exactly the same, even as people wearing the same shoe size might not have the same foot dimensions (refer to chapter 6, sub-section 6.6). This is in agreement with what is obtained in the literature (Olivato, et al. 2007; Hawes, 1994; Goonetilleke 2003; Broussard 2002) which shows that most people's feet are two different sizes. These findings further concretised the argument of Pezza (2011) that it is rare to find a diabetic patient who is wearing the proper shoe size and width.

Therefore, the data presented in this thesis bring out the need for extra emphasis on accurate measurement of the foot in order to make shoes to an individual's correct shoe size and to eliminate guess work. These findings are found to be very significant as the relation between foot shape and shoe shape is seen as a cause of discomfort, foot problems, or even injury due to the fact that an individual's shoe size and foot size can differ appreciably. It was concluded that to provide the best fit of footwear for the diabetic population, correct measurement of their feet should be carried out before they buy shoes or footwear is made for them.

At this point in the work, a normal last was used to make trial prototypes. Note that a clear description of the materials and methods used to make and assess the prototypes were outlined in sub-sections 7.4.1 & 7.4.2. The dimensions of the last were critically looked into and the outcome of the trial prototypes for fitting and comfort factors point to the fact that some parts of the last would require amendments in order to properly accommodate minor foot deformities. However, the majority of patients can use footwear made from the normal last. It was also discovered from the study that sandals are well accepted by potential users in Nigeria, especially in the Northern Region. In regards to shoe size, the survey showed that shoe size 42 or 8 is the most popular size for male subjects whereas size 40 is seen as the most widely used size among female subjects.

A visual and fitting or comfort assessment of the prototypes showed high acceptability by the intended users of the product. Similarly, feedback received from medical doctors and footwear designers/ technicians was very positive. The doctors believe that the product would be beneficial to diabetic patients if the prototypes are fully developed, produced and made available to diabetic patients.

Consequently, a research framework was developed (see fig. 7.17) as a representation of the output of the research findings. The framework gives three step-by-step procedures for provision of appropriate footwear to people suffering with diabetes.

In conclusion, this study demonstrates that diabetic patients who are at risk of developing foot ulcers or wounds and who do not require custom shoes may benefit from this type of footwear.

6. To identify areas for further research.

This study has led to the discovery of many areas that would require further investigations as outlined in sub-section 9. 7.

9.3 Limitations of the research

Even though it could be argued that this research was carried out at different hospitals in Northern Nigeria that admit patients from different regions of the country and employ the services of professionals trained at universities across the country and from overseas, still, generalizations of the findings of this study should be made with caution. In addition, even though all the respondents and interviewees were diabetic patients and qualified practitioners (medical doctors) respectively (see sub-sections 3.4.1 & 4.6); there is a lack of perspective of other health professionals like orthotist, podiatrist, nurses etc. For a complete view of the role of diabetic footwear in the prevention of diabetic foot complications, their opinions should be included. Additionally, prospective studies that could evaluate the impact of footwear practices on outcomes such as foot ulcers and amputations would further help to determine the potential for interventions to improve practice and reduce complications.

Another weakness of this study is the sample size for both the interview and questionnaire surveys. To improve the reliability of the results, involvement of more subjects is recommended. Additionally, measurement of feet was done using simple but accurate tools and procedures. The use of more advanced technological devices and equipment may improve the reliability of foot measurement.

The experimental analysis of shoe upper materials was carried out only on the most widely-used material for the construction of footwear. Analysis of different materials use for shoe upper would give a clearer picture of their unique properties.

9.4 Contributions to knowledge

This research provides the latest insights on different areas related to diabetes, diabetic foot complications, diabetic footwear materials and design, diabetic footwear, etc. The key original contributions from this research are outlined thus:

1. The research investigated the scale or nature of diabetic foot problems experienced by people suffering with the condition from a developing country. Researchers (Tagang 2010; Abbas & Archibald 2007; Mbanya 2006;) have shown that data on diabetes and diabetic foot problems from developing countries, particularly of Africa, are very poor. The outcomes of this project provide information not only on diabetes but also on the nature of diabetic foot problems.

2. The popularity of using slippers and other types of inappropriate footwear by diabetic patients in this part of the world was established through interview, questionnaire and market surveys. This research revealed that financial constraints among other factors are the main barriers to use of appropriate footwear in the region. Many use cheap footwear regardless whether they provide the required protection and comfort to their feet or not.

3. Product Design Specification (PDS) was developed and used to make the research trial prototypes. The specification has brought out a range of very important elements that could guide manufacturers, researchers and product developers/designers on key design factors.

4. A research framework (see fig.7.17) was developed that would help to identify diabetic patients with special needs of footwear and to provide them with suitable products. It was designed to be used along with the PDS mentioned above to give clear guidance on appropriate design features or elements for diabetic footwear manufacture. The materials selection component of the framework in particularly is considered a key element of the original contribution of this work that could be of great benefit to researchers, industrialists, etc both in the developed and underdeveloped countries. It would provide manufacturers with a better understanding of suitable diabetic footwear materials selection and would also be useful for their costing and supply chain. The framework would also help potential users to anticipate the nature and features of the end product to be supplied to them.

5. Last but not least, this research has yielded an original journal article (see appendix XXIII) and provides areas for further study. It is believed that additional publications of this research findings will serve as a catalyst for further research in the subject area.

9.5 Collaboration

During the course of this project, some health providers in Nigeria showed interest for collaboration with the researcher on how the proposed design framework could be implemented for the benefit of diabetic patients in the country. Consequently, collaboration between Ahmadu Bello University Teaching Hospital (ABUTH) Shika and the Nigerian Institute of Leather and Science Technology (NILEST), Zaria for development of appropriate footwear for diabetic patients was initiated. The key persons involved in the collaboration effort between the two institutions apart from the chief investigator (the author) are; the Head of Department, Orthopaedic and Trauma, ABUTH and the Director General and Chief Executive Officer, NILEST. Refer to appendix XXII for the names and e-mail addresses of the persons involved and their institutions of affiliation.

Whereas ABUTH is a tertiary hospital, NILEST is a higher institution with a mandate of training and research on leather and leather products (footwear being a key department in the institution) with research centres in all the Northern Geopolitical Zones of Nigeria.

The centres are located at Sokoto (North West), Jos (North Central), Maiduguri (North East) and Kano (North West). While ABUTH would provide the medical expertise, NILEST would meet all the design and technical requirements of the project. It is believed that through this collaboration, a fully functioning multidisciplinary team (with a wide range of expertise) could have dramatic impact on the foot-care and well-being of diabetic patients in Nigeria.

9.6 Reflections from the research.

The figure below (fig. 9.1) gives a graphic representation of the PhD journey. The major activities carried out each year (from 2011 to 2014) in the course of the project are pointed out. The Gantt chart (refer to appendix II) developed at the beginning of the study was a very useful tool that helped the researcher to manage the project and stay on schedule. It should be made clear that the researcher training courses (managing research and references, planning and managing research, literature searching and reference management, writing skills, taking a critical approach to your research, publishing research findings, etc) attended by the author at the DMU Leicester provided the researcher with excellent knowledge of research methodology and related relevant tools for carrying out effective research. Consequently, the researcher presented research findings to professional meetings in Nigeria. Furthermore the doctorate degree experience afforded the researcher the opportunity to develop a strong intellectual grasp of writing research proposals, formulation of standard operating procedures for interviewing professionals and conducting questionnaire surveys.

Other key activities undertaken in the course of the research included visiting clinics/ hospitals, companies, laboratories for materials analysis, etc. Also, the researcher's recent training on Information Technology (IT) at DMU on Creating and Managing Large Documents, Effective Presentation Using Power Point, Managing Data with Excel etc, have further equipped him on handling large documents and analyzing data using different computer packages.

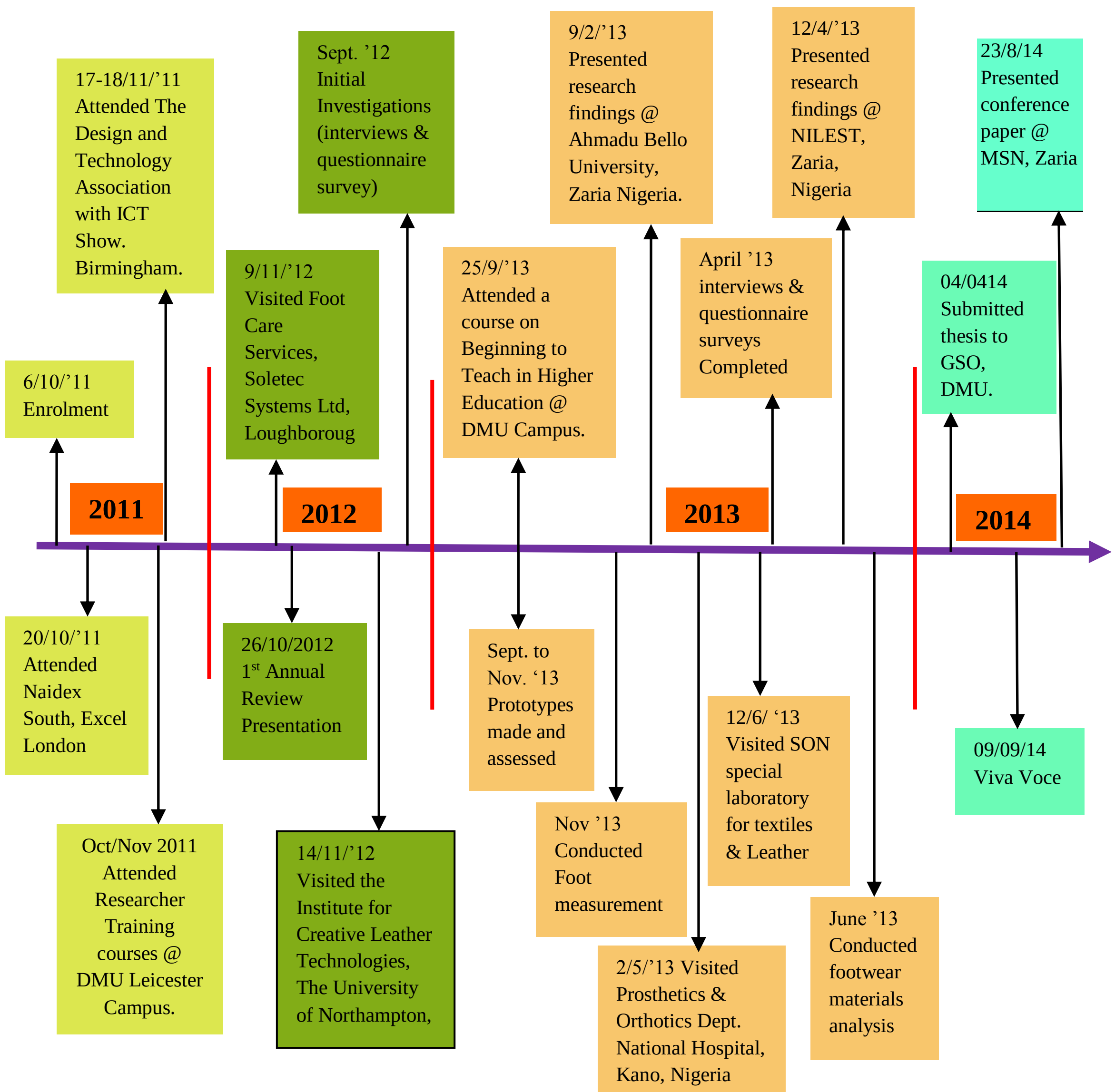


Fig. 9.1 Activity time line.

9.7 Recommendations for future work.

This study has identified certain areas that would require further investigation. The key aspects identified are outlined below.

1. It was pointed out in the introduction (sub-section 1.5) that a comprehensive technical understanding of diabetic footwear materials is still lacking. In this study an analysis of footwear materials was carried out as an attempt to investigate physical properties of shoe upper leathers for their suitability for diabetic footwear or otherwise. However, the author suggests that further investigations on different upper materials and composite specimens of both upper and lining should be conducted. Furthermore, it is strongly recommended that further tests should be done on soling materials and insoles to establish the best material combination options that would improve foot health.

2. The author recommends that a study on how diabetic patients would be effectively educated about the role of footwear in the management of diabetic foot problems should focus more on prevention. However, emphasis should also be made on how footwear could be used as an effective treatment strategy by using materials that are culturally/ environmentally acceptable and appropriate footwear designs.

3. A research on how clinicians would be able to work closely with footwear manufacturers/ retailers to develop a guideline for buying good footwear to assist consumers in selection of healthy footwear.

4. The researcher has discovered a professional gap in persons qualified to provide correct footwear fitting in the country. He is therefore with the opinion that researchers should study ways that government and non-governmental

organizations could encourage persons with interest and required basic knowledge to be trained effectively to meet this important need.

5. More research on how to make footwear more comfortable, functional and yet aesthetic for customers with health challenges in their feet should be carried out urgently.

6. The sample size for some aspects of this study was found to be small. It is therefore recommended that a similar study with a larger sample size should be carried out. In particular, further data should be gathered through interview surveys involving major health professionals involved in the management of diabetes and diabetic foot.

7. A study on how to encourage a multidisciplinary approach to addressing diabetic foot problems in Nigeria is advocated.

8. For future work, the author recommends the use of more advanced technological equipment like laser scanning devices that can records hundreds of measurements of specific important positions of the foot.

These areas identified for further studies are considered very important as the findings of the study itself. It is therefore strongly suggested that these aspects should be explored in order to improve the experiences of diabetic patients in regards to footwear.

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APPENDICES

Appendix I

Time Management Plan

Task	Earliest Start	Length (Weeks)	Type of task x (Sequential) y (Parallel)	Dependent on:
1.1 To plan for information search	Oct. 2011	1	x	Research topic
1.2 Collect books & articles	Oct. 2011	12	x	1.1
1.3 review and analyze relevant literature	Oct. 2011	130	y	1.2
2.1 Plan for questionnaire & interview surveys (apply for ethical approval)	Jan. 2012	8	x	1.3
2.2 To Prepare questionnaires	Feb. 2012	8	x	1.3
2.3 Prepare structured interview questions	March 2012	8	x	1.3
3.1 To carry out initial investigations (questionnaire & interview surveys)	May 2012	16	x	2.2 & 2.3
3.2 To analyze results of the initial investigation	Sept. 2012	4	x	3.1
4.1 Plan for questionnaire survey	Oct. 2012	6	x	1.3 & 3.2
4.2 To conduct questionnaire survey	Nov. 2012	16	x	4.1
4.3 To collect back filled questionnaires.	Nov. 2012	16	x	4.2
4.4 Analyze outcome of the questionnaire survey	March 2013	4	x	4.3
5.1 To plan for interview survey (make appointment with interviewees)	Oct. 2012	6	y	1.3 & 3.2
5.2 To conduct interview	Dec. 2012	18	y	5.1
5.3 Analyze the outcome of the structured interview	April 2013	4	y	5.1

6.1 Plan for experimental analysis (collect footwear materials)	May 2013	4	x	1.3, 3.1, 4.4 & 5.3
6.2 Conduct footwear materials analysis	May 2013	8	x	6.1
6.3 Analyze results	July 2013	4	x	6.2
7.1 To develop footwear design models	Aug. 2013	4	x	1.3, 3.1, 4.4 & 5.3
7.2 To sample patients' opinion on desired design models	Sept. 2013	2	x	7.1
7.3 To make trial prototype of the product	Sept. 2013	4	x	6.3 & 7.2
7.4 Evaluate product prototype	Oct. 2013	4	x	7.3
8.1 To write thesis	Nov. 2013	26	x	All the above activities
8.2 Print, bind and submit thesis	May 2014	2	x	8.1

Check points: Enrollment-Oct. 2011; Submission of IntPhD Study Protocol Document- Dec. 2011; Submission of Registration Form-March, 2012; Submission of Ethics Form-March 2012; Visit DMU/ 1st Annual Review- October 2012; Visit DMU/ 2nd Annual Review-Oct. 2013 & Submission of Thesis-March 2014.

Appendix II
Gantt Chart

Year	Tasks	10	11	12	01	02	03	04	05	06	07	08	09
1 (2011/2012)	1.Researcher Training	C_1											
	2.Plan for Lit. Review			C_2									
	2.1 Collect Materials						C_3						
	2.2 Review relevant lit.												
	3.Plan for quest. survey						C_4						
	3.1 Prepare questions												
	3.2 Conduct survey												
	3.3 Collect & anal. data												
	4.0 Plan for interv. survey												
	4.1 Make Appointment. with Interviwees												
2 (2012/ 2013	4.2 Prep.questions & SOP												
	4.3 Conduct interview & record information	C_5											
	4.4 Analyze data												
	5.0 Plan for Experiment												
	5.1 Collect materials												
	5.2 carry out experiment												
	5.3 Record & analyze results												
	6.0 Prepare seminar paper												
	7.0 Develop prototypes												
	7.1 Design prototypes												
	7.2 Collect materials												
3 (2013/ 2014	7.3 make prototypes												
	7.4 Assess prototypes	C_6											
	7.5 Re-design prototypes												
	7.6 Re-make prototypes												

	7.7 Re-assess prototypes												
	7.8 Develop conclusion												
	8.0 Write Thesis												C_7

Key: **0**1**=** Jan.**; 02**= Feb.; **03**= Mar; **04**= April; **05**= May; **06**= Jun; **07**= Jul; **08**= Aug.; **09**= Sept.; **10**= Oct.; **11**= Nov.; **12**= Dec. Check Points: **C_1** – Enrollment. **C_2** -Submission of IntPhD Study Protocol Document. **C3** -Submission of Registration Form. **C_4** -Submission of Ethics Form. **C_5** – Visit DMU/ 1st Annual Review **C_6** – Visit DMU/ 2nd Annual Review. **C_7** - Submission of Thesis.

Appendix III
Example of Monthly Progress Report

Progress Report

Student:	Jerry Tagang	**Student Number:**	p08286677	**Faculty:**	Faculty of Art, Design and Humanities		
Programme:	Art And Design	**Year:**	1	**First Supervisor:**	Chien-Chung Chen	**Second Supervisors:**	Nick Higgett , Philip Stewart
Attendees:	Dr. Robert Chen And Jerry Tagang					**Type of Discussion:**	Face to face
Date of Meeting:	10/10/11	**Date & time of next meeting:**					

Issues Discussed
Introduction: The first supervisor, Dr. Robert Chen welcomed the student, Jerry Tagang back to De Montfort University and asked him if he is still interesting in carrying out his research based on the initial proposal he submitted with his application form. The student affirmed that he would still base his research on that proposal- developing bespoke footwear for people living with diabetes. Research Approach The supervisor then advised that the approach to the work would be research with support of making appropriate footwear. **Research plan** Dr. Robert outlined the important dates that the researcher would need to take into consideration or put in his diary as follows: 1. 1-3 months - to make clear plans for the research. 2. 1-6 months - to complete and submit registration form for the research degree. 3. 1-12 months - to carry out intensive literature review. 4. 6-12 months - To make plans for primary research. 5. 13-24 months - to conduct primary research.

6. 25-30 months- to analyze research data.

7. 31-36 months- to write up the thesis.

Practical support

The supervisor pointed out that Mr. Bill Bird would be contacted to become an advisor for some practical aspect of the research and for the researcher to use his facilities at Birmingham to gain practical experience. He also said that Mr. Phil Steward would always be available to give the researcher the required technical support at the University.

Hospital Experts

The first supervisor tasked the researcher to identify and contact hospital experts in his home country, Nigeria that would provide him with the required information for his study.

Time management

The researcher was urged by the supervisor to bear in mind that his time must be managed well to enable him to handle his office work, family commitment alongside his research activities.

References

How to handle references effectively was another major thing that the supervisor drawn the attention of the research to take note of. He asked the student to provide at least five positive and five negative references that deals with the subject matter.

Actions for student

1.To make a clear study plans/ registration

2.To search for appropriate references (at least ten)

3.To inform Mr. Phil Stewart to arrange a meeting between the student and Mr. Bill Bird

Actions for supervisor

1.To request Mr. Bill Bird to play the role of an adviser in the research

2.To give the student a copy of his thesis

Agenda for the next meeting

Supervisor Comments

Discussed registration.

Appendix IV
Questionnaire Survey

This questionnaire is designed to carry out a survey on the role of footwear in the management of diabetes foot problems. The researcher, Jerry I. Tagang is a PhD student at De Montfort University, Leicester, United Kingdom. The information given will be handled/ treated confidentially and for academic purposes only. You are free to discontinue your participation in this survey at any point without given a reason. Thank you.

Please **tick or mark** [with **X**] the appropriate option.

Part I. Personal Information

1. Gender. a. Male □ b. Female □ c. Do not want to mention □

2. Age. a. ≤ 20yrs□ b. 21-35yrs □ c. 36- 50yrs □d. 51-65yrs□e. ≥ 66yrs □

3. Occupation.

a. Employed □ b. Own Business □ c. Unemployed □ d. Retired □ e. Student □ f. Farmer □

g. Housewife □ h. Others………………………………………………

4. Where do you live? a. Rural area □ b. Urban □ c. Do not want to mention □

5. Are you suffering with diabetes? Yes □ No □ **If yes** what type? a.Type 1 □ b. Type 2 □

6. How long have you being living with diabetes?

a. ≤ 5yrs □ b. 6-10yrs □ c. 11-15yrs □ d. 16-20yrs □ e. ≥ 21yrs □

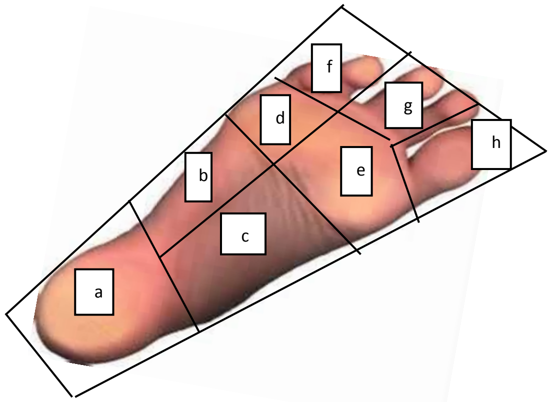
Part II. Information on Diabetes Foot Care and Foot Problems

7. Have you had your feet checked by a doctor or a health professional? Yes □ No □

8. Have you ever reported or complained of any numbness or pain in your feet to your doctor or other health care professional? Yes □ No □

9. Do you have foot problems (e.g, ulcer, wound, gangrene, etc)? Yes □ No □

If yes, indicate on the pictorial grids with (X) on any of the diagrams given below (fig.1)



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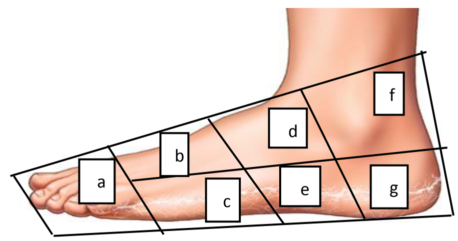

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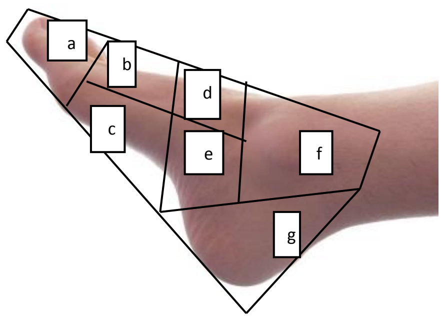


Ic

Fig.1. Different views of the Human foot-I

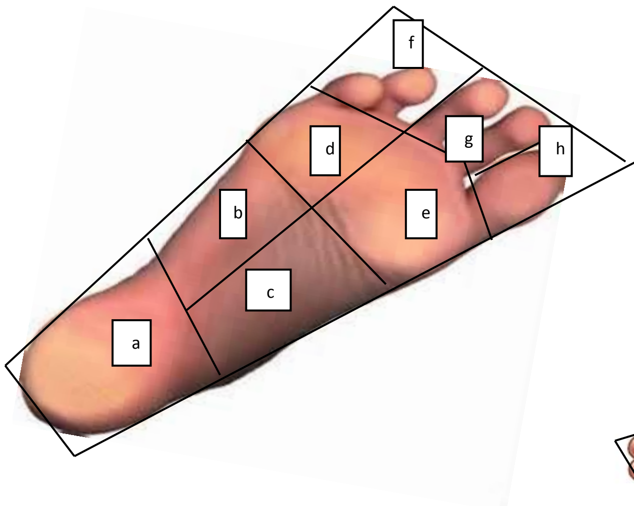
Part III. Foot problems developed as a result of using inappropriate footwear

10. Do your shoes give you discomfort (e.g cause you pain or injury)? Yes □ No □

11. Do you experience blisters or redness on your feet from wearing your shoes? Yes □ No □

12. If your shoes cause you pain/ Injury, what are the reasons?
a. Shoes are too tight □
b. Shoes are rubbing my feet □
c. Shoes are pinching my feet □
d. Other reasons (please write)………………………………………………

13. From the diagrams below (fig. 2), please indicate area(s) of particular sensitivity or pains (if any) caused by your footwear (with **1** being very painful and **5** being not very painful)



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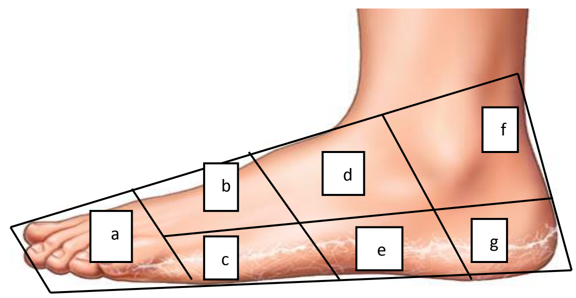

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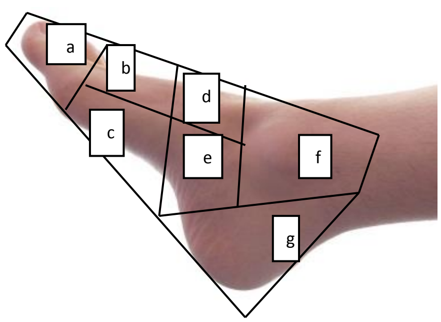


IIc

Fig.2.Different views of the Human foot II

Part IV. Footwear Fitting/ Features

14. Do you have foot problems that make it difficult for regular shoes to accommodate your feet?

Yes □ No □. **If yes** describe (e.g ulcer, gangre, wound, etc)

…………………………………………………………………………………………

15. Do you think your shoes need modification in order to accommodate your feet well?

Yes □ No □

16. Do you think 'good' footwear can improve your foot condition and allow you to walk better?
a. Yes □ b. No □ c. Do not know □

17. Are there times you walk without shoes or bare foot? Yes □ No □

18. Do you have difficulties in putting shoes on or taking off your shoes? Yes □ No □

19. Do you wear shoes without socks? Yes □ No □

20. What type of footwear do you use often?
a. Shoes □
b. Half-shoes □
c. Sandals □
d. Boots □
e. Slippers □
f. Custom-moulded □
g. Sport shoes or Sneakers □
f. Others (please write)…………………………………………………………

21. Are you comfortable with your shoes? Yes □ No □

22. Do you receive information about the type of footwear you should wear? Yes □ No □
If yes, write the source…………………………………………………………

23. What is your view on the soles of your shoes?
a. The soles of my shoes are too flexible □
b. The soles of my shoes are too rigid □
c. The soles of my shoes are neither too flexible non too rigid □
d. Do not know □

24. Do you know your correct shoe size? Yes □ No □

25. Do your shoes fit well? Yes □ No □

26. Do you think you need different sizes of shoes for your feet (left and right)? Yes □ No □

27. If your doctor prescribes specially designed footwear with extra insert materials as insoles would you be happy to wear them? a.Yes □ b. No □ c. Not sure □

28. What type of heel construction do you choose for your shoes? You can tick more than one option. a. High heel □ b. Medium Heel □ c. Low heel □ d. Flat heel □

29. What type of shoe do you wear most often? You can tick more than one option.
a.Lace fastening shoe □ b.Buckle fastening shoe □ c.Velcro fastening shoe □ d. Un- fasten/ Slip-on shoe.

30. What type of upper materials do you choose for your shoes? You can tick more than one option. a. Leather □ b. Synthetic □ c. Fabric □ d. Others (please write)
……………………………………………………………………………….

31. How often do you buy shoes?
a. Quarterly □ b. Twice a year □ c. Once a year □ d. Less often than once a year □

32. How much are you always willing to spend on a pair of shoes? ₦……………….

33. If your doctor recommends footwear that will cost you double the amount you usually spend on shoes, would you be willing to buy them? Yes □ No □

34. When purchasing or selecting footwear, what are your most preferred elements?
Rank the following (with **1** for the most preferred and **13** for the least preferred).
a. Style/ Fashion □
b. Weight □
c. Sole □
d. Heel □
e. Comfort □
f. Brand □
g. Color □
h. Quality □
i. Protection □
j. Adjustability □
k. Durability □
l. Breathability □

35. Do you have any comments about diabetes and footwear?
....

Thank you for your participation in this survey.

Appendix V
Structure Interview questionnaire

The Graduate School

De Montfort University,

Leicester, United Kingdom.

Research Information Sheet

As part of my PhD studies at De Montfort University, I am required to undertake a research study titled: *An Investigation into footwear materials choices and design for people suffering with diabetes.*

I am intending to conduct an interview and questionnaire survey in order to understand more about the subject.

This survey has been given ethical approval by:

1. The Ministry of Health, Kaduna State
2. Ahmadu Bello University Teaching Hospital, Zaria
3. De Montfort University, Leicester, United Kingdom.

The resulting information would be used as part of my university thesis. The thesis would be read by academic staff at the university and may be seen by another external examiner.

You have the right to withdraw from the study without giving a reason.

I will endeavor to make sure that your records are kept confidential and it will be stored in a secure place and destroy after the thesis has been completed.

Thank you.

My contact details:

Irmiya J. Tagang
The Graduate School
John Whitehead, Leicester, UK
E: jerrytagang@yahoo.com
T: +234 (0)8036422329. Or
Nigerian Institute of Leather and Science Technology, Zaria, Nigeria.

1st Supervisor's contact details:
Dr. Robert C. Chen
Principal Lecturer,
Industrial Design and Orthopaedic footwear Technology,
De Montfort University, Leicester, UK.
T: +44(0)1162577565
E: rchen1@dmu.ac.uk
B: http://ucdgroup.blogspot.com/

2nd Supervisors' contact details:
Nick Higgett
De Montfort University.
E: nph@dmu.ac.uk

Dr. Eujin Pei
De Montfort University.
E: epei@dmu.ac.uk
W: www.eujinpei.our.dmu.ac.uk

Consent form

Research Topic: *An Investigation into footwear materials choices and design for people suffering with diabetes.*

I have read the attached information sheet [ ]

I understand the purpose of the study and what I am being asked to do [ ]

I am aware that I can withdraw without giving a reason [ ]

I give consent that the information collected to be included in a university thesis [ ]

Consent given by:

Name:

Signature:

Date:

Researcher:

Jerry I. Tagang

The Graduate School, John Whitehead,

The Gateway Leicester,

E: jerrytagang@yahoo.com

Part I- Personal Information

1. How many years have you been practicing?

a. ≤ 5yrs □ b. 5-10yrs □ c. 11-15yrs □ d.16-20yrs □ e. ≥ 20yrs □

2. What is your area of specialization? ……………………………………………

3. Which type of diabetes do you treat mostly? a. Type 1 □ b. Type 2 □

Part II- Information on diabetes and foot care services

4. Do you have a diabetic clinic in your hospital? Yes □ No □

5. Do you offer foot care for diabetic patients in your hospital? Yes □ No □

6. How often do you examine your diabetic patients' feet?

a. Twice a year □ b. Once a year □ c. Not at all □

7. How often do you refer diabetic patients with foot problems to orthopaedic specialists?
a. Regularly □ b. Occasionally □ c. Not at all □

8. Provisions of professional foot care, e.g podiatric services are not available or common in Nigeria.
a. Strongly agree □ b. Agree □ c. Disagree □ d. Strongly disagree □ e. Do not know □

Part III- Diabetic Foot Problems

9. Have your diabetic patients ever reported or complained of any pain or numbness to their feet?

Yes □ No □ **If yes**, how many percent of diabetic patients do make such complaints?

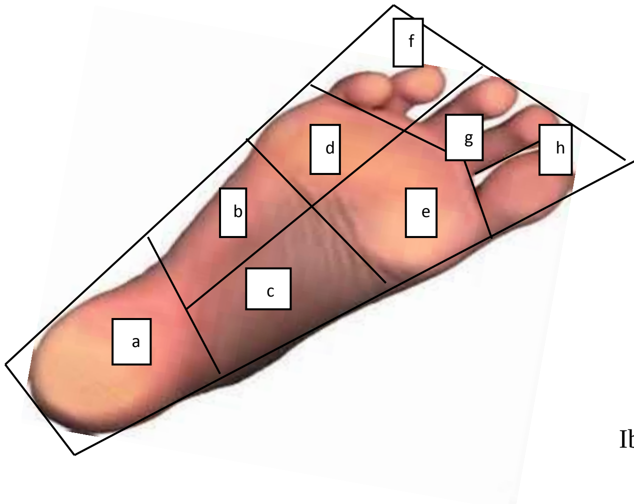
a. 1-20% □ b. 21-40% □ c. 41-60% □ d. 61-80% □ e. 81-100% □

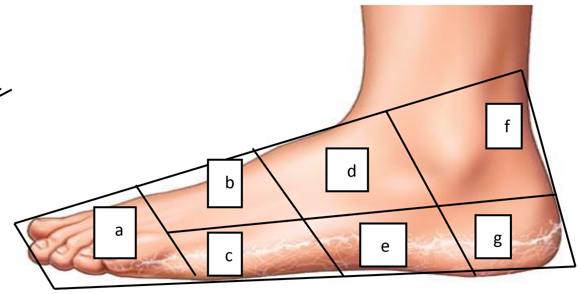
10. Do you think the majority of your diabetic patients' feet are at risk of developing ulcers? Yes □ No

11. How many percent (%) of your diabetic patients have foot problems?

a. 1-20% □ b. 21-40% □ c. 41-60% □ d. 61-80% □ e. 81-100% □

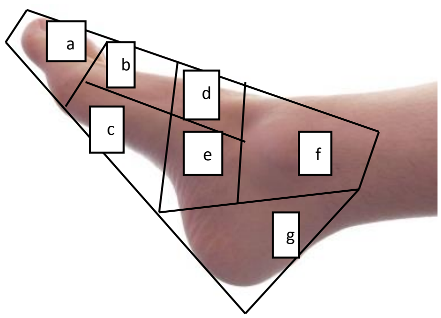
12. From your experience, which part(s) of diabetic foot is mostly ulcerated? Indicate on the diagram(s) below.





Ib

Ia



Ic

Fig. 1. Different views of the Human foot

13. What percentage of people with diabetes foot problems received foot amputation?

a. 1-20% □ b. 21-40% □ c. 41-60% □ d. 61-80% □ e. 81-100% □

14. In your opinion, what is the best strategy to adopt for prevention of diabetic foot problems?

Please **rank** the following (with **1** being the most effective and **5** being the least effective).

a. Improving glycemic control □

b. Improving blood pressure / lipid control □

c. Self-management and education □

d. Use of appropriate footwear □

e. others (please write)…………………….……………………………………

Part IV- Diabetes and Footwear Related Issues

15. Foot ulcers are related to pressure from footwear that is too narrow or otherwise inadequate. a. Strongly agree □ b. Agree □ c. Disagree □ d. Strongly disagree □ e. Do not know □

16. Have your patients ever reported any bad footwear experiences? Yes □ No □

If **yes**, of what nature?..

17. Are there often diabetic foot problems relating to a particular aspect or part of footwear? Yes □ No □

If **yes**, please describe……………………………………………………………………

18. What is the experience of amputees with regards to footwear before their operation?

………………………………………………………………………………………………

19. Do you think ill-fit footwear could be one of the major problems that lead to foot amputations?

Yes □ No □

20. Risk of foot amputation may double for diabetic patients who do not obtain prescribed (specially designed) footwear. a. Strongly agree □ b. Agree □ c. Disagree □ d. Strongly disagree □

e. Do not know □

21. Are regular shoes able to accommodate the foot of diabetic patients? Yes □ No □

If **no**, what is the percentage that cannot use regular footwear?

a. 1-20% □ b. 21-40% □ c. 41-60% □ d. 61- 80% □ e. 81-100% □

22. What features of footwear could be emphasized or prescribed for diabetic patients? Please **rank** the following (with **1** being the best and **7** being the least).

a. Proper Fitting □

b. Cushioning □

c. Light weight □

d. Durability □

e. Comfortability □

f. Breathability □

g. Others (please write)..

23. Do you think prescriptive footwear can be sourced locally?

a.Yes □ b. No □ c. Do not know □

24. It seems there are no footwear makers or technicians with knowledge of footwear modification in Nigeria that can make shoes to the requirements of your patients' foot problems. a. Very much agree □ b. Agree □ c. Disagree □ d. very much disagree □ e. Do not know □

25. Footwear available in Nigeria markets are not meeting foot care requirements of diabetic patients.

a. Very much agree □ b. Agree □ c. Disagree □ d. very much disagree □ e. Do not know □

26. What type of footwear do your **male** patients use often?

a. Shoes □
b. Half-shoes □
c. Sandals □
d. Boots □
e. Slippers □
f. Sport shoes or Sneakers □
g. Custom-moulded □
h. Others (please write) ………………………………………………………..........

27. What type of footwear do your **female** patients use often?

a. Shoes □
b. Half-shoes □
c. Sandals □
d. Boots □
e. Slippers □
f. Sport shoes or Sneakers □
g. Custom-moulded □
h. Others (please write) ……………………………………………………………

28. What type of heel construction would you choose for diabetic shoes? You can tick more than one option. a. High heel □ b. Medium Heel □ c. Low heel □ d. Flat heel □

29. What type of footwear would you prefer for people suffering with diabetes to wear most often? You can tick more than one option.

a. Lace fastening shoe □ b. Slip-on shoe □ c. Buckle fastening shoe □ d. Velcro fastening shoe □

30. What type of shoe upper materials would you choose for your diabetic patients? You can tick more than one option. a. Leather □ b. Synthetic □ c. Fabric □

d. Others (please write)……………………………………………………………………………..

31. Do you think your diabetic patients are happy to use special footwear (e.g orthopaedic)? Yes □ No □

If **no**, please give reasons…………………………………………………………………………

32. Do you think footwear should be regarded as an important consideration in the clinical management of many foot disorders or problems? Yes □ No □

33. Are you aware of any foot care programme for diabetic patients in Nigeria? Yes □ No □

If **yes,** please explain……………………………………………..

34. Are you aware of any footwear programme for diabetic patients in Nigeria? Yes □ No □

If **yes,** please explain……………………………………………………….

35. Do you think that medical specialists or clinicians have need for further education about prescription of orthopaedic/ therapeutic footwear to patients with foot problems? Yes [   ]   No [   ]

36. Any other comments?

……

…….

Thank you.

Appendix VI
Shoe sizing system

Shoe sizing systems vary across the world. Conversion charts for the various international sizing conventions are listed below:

Adult Shoe Sizes

International System		Sizes															
Europe		35	35½	36	37	37½	38	38½	39	40	41	42	43	44	45	46½	48½
Mexico							4.5	5	5.5	6	6.5	7	7.5	9	10	11	12.5
Japan	**Mens**	21.5	22	22.5	23	23.5	24	24.5	25	25.5	26	26.5	27.5	28.5	29.5	30.5	31.5
	Womens	21	21.5	22	22.5	23	23.5	24	24.5	25	25.5	26	27	28	29	30	31
U.K.	**Mens**	3	3½	4	4½	5	5½	6	6½	7	7½	8	8½	10	11	12	13½
	Womens	2½	3	3½	4	4½	5	5½	6	6½	7	7½	8	9½	10½	11½	13
Australia	**Mens**	3	3½	4	4½	5	5½	6	6½	7	7½	8	8½	10	11	12	13½
	Womens	3½	4	4½	5	5½	6	6½	7	7½	8	8½	9	10½	11½	12½	14
U.S. & Canada	**Mens**	3½	4	4½	5	5½	6	6½	7	7½	8	8½	9	10½	11½	12½	14
	Womens	5	5½	6	6½	7	7½	8	8½	9	9½	10	10.5	12	13	14	15.5
Russia & Ukraine	**Womens**	33½	34		35		36		37		38		39				
Korea (mm.)		228	231	235	238	241	245	248	251	254	257	260	267	273	279	286	292
Inches		9	91/8	9¼	93/8	9½	95/8	9¾	97/8	10	101/8	10¼	10½	10¾	11	11¼	11½
Centimeters		22.8	23.1	23.5	23.8	24.1	24.5	24.8	25.1	25.4	25.7	26	26.7	27.3	27.9	28.6	29.2
Mondopoint		228	231	235	238	241	245	248	251	254	257	260	267	273	279	286	292

Girl Shoe Sizes

Europe	26	26.5	27	27.5	28	28.5	29	30	30.5	31	31.5	32.2	33	33.5	34	35
Japan	14.5	15	15.5	16	16.5	17	17.5	18	18.5	19	19.5	20	20.5	21	21.5	22
U.K.	8	8.5	9	9.5	10	10.5	11	11.5	12	12.5	13	13.5	1	1.5	2	2.5
U.S. & Canada	9.5	10	10.5	11	11.5	12	12.5	13	13.5	1	1.5	2	2.5	3	3.5	4

Boy Shoe Sizes

Europe	29	29.7	30.5	31	31.5	33	33.5	34	34.7	35	35.5	36	37	37.5
Japan	16.5	17	17.5	18	18.5	19	19.5	20	20.5	21	21.5	22	22.5	23
U.K.	11	11.5	12	12.5	13	13.5	1	1.5	2	2.5	3	3.5	4	4.5
U.S. & Canada	11.5	12	12.5	13	13.5	1	1.5	2	2.5	3	3.5	4	4.5	5

Shoe Sizing: Shoe Guide Org. (2006). Available at: http://www.shoeguide.org/Shoe_Sizing (Accessed on 01/08/2013). Shoe size is a numerical scale for the size of a shoe, which aids people in selecting an appropriate shoe size.

Appendix VII

Standard Operating Procedure for Questionnaires Survey

Procedure | **Enquiry** | Response

At the hospital general reception

- Hello, I am a research student from DMU, Leicester, UK.
- Where is the diabetic clinic located?
- Thank you.

……………
……………
……………

At the reception of the diabetes clinic

- Hello, I am a research student from DMU, Leicester, UK.
- Where is the office of the consultant In-charge of the diabetes clinic located?
- Thank you.

……………
……………
……………

At the office of the consultant In-charge of the diabetes clinic

- Hello, I am a research student from DMU, Leicester. I have been given ethical approval by your hospital management to conduct questionnaires and Interview surveys (among diabetic patients and doctors) in your hospital.
- Will you give me permission to conduct the survey in your clinic?
- Will you allow me to carry out the survey for a period of 6-8weeks?
-Which day do you attend to your diabetic patients in the clinic?
-Thank you.

Yes ☐
No ☐

Yes ☐
No ☐

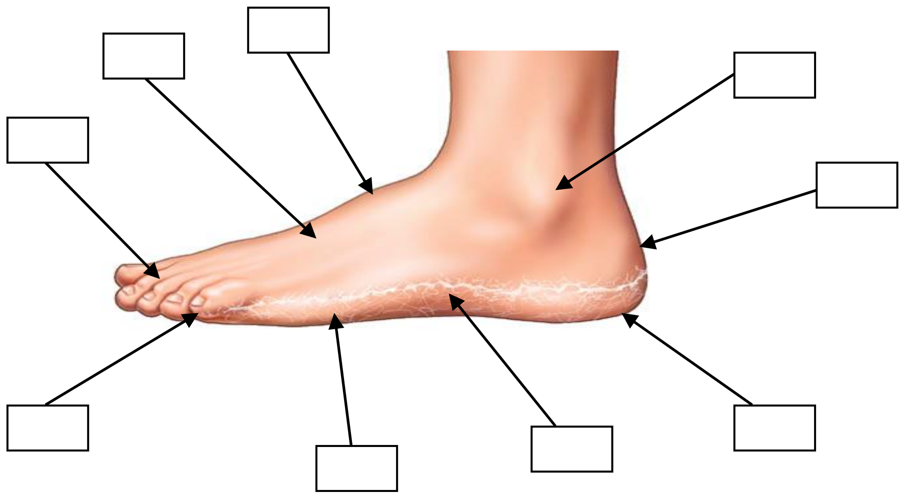
……………

Distribution of questionnaires to diabetic patients

- Hello, I am a research student from DMU, Leicester, UK. I am carrying out a survey on 'footwear material choices and design for people suffering with diabetes'.
- Please, can you spare five minutes to fill my research questionnaire?
- Thank you.

Yes ☐
No ☐

Appendix VIII
One view of the human foot Image



The human foot

Appendix IX
Photos of patients at a diabetic clinic

Photos of patients at a diabetic clinic showing the types of footwear they wear often. The photographs show that majority of people suffering with diabetic in Nigeria, particularly in Northern Region wear slippers or slip-on footwear most times.

Appendix X
Commonly use footwear in Nigeria (particularly in the Northern Region)

Most of the patients wear slippers (with straps without back support) and sandals as shown below.









Appendix XI (a)
DMU Ethical Approval for this research (Signatory page)

C1 08/09

C1 08/09

(6) A statement of your competence to carry out this research as a student or a brief one page curriculum vitae for each applicant, including recent publications (staff only)
(7) Other documentation as advised necessary:

There are normally four possible outcomes from reviewing the activity against the procedures in place:

1. no ethical issues
2. minor ethical issues which have been addressed and concerns resolved
3. major ethical issues which have been addressed and concerns resolved
4. ethical issues that have not been resolved/addressed

Provisional approval could be given at the discretion of the Research Ethics Committee.

Authorisation is dependent on Faculty. Please refer to your faculty guidelines for details on how outcomes are reached:

- The reviewer advises the PMB/SAB/REC of those activities in the first three outcomes.
- Activities in the fourth outcome are submitted to the Faculty REC for resolution
- The approved form must be kept with project documents, e.g. be included as an appendix in the report.

Signature of researcher / student Date 15-10-2012

Signature of supervisor Date 15-10-2012

Line Manager or Head of School signature (Staff only) Date 24/10/12

This form complies with the DMU policy statement on Human Research Ethics, a full copy of which can be found in the General Regulations and Procedures Affecting Students.

A separate form is required for each project.

ADVANCE APPROVAL OF RESEARCH ACTIVITY INVOLVING HUMAN RESEARCH ETHICS

1 Respondents' co-operation in a research project is entirely voluntary at all stages. They must not be misled when being asked for co-operation.

2 Respondents' anonymity must be strictly preserved. If the Respondent on request from the Researcher has given permission for data to be passed on in a form which allows that Respondent to be identified personally:

(a) the Respondent must first have been told to whom the information would be supplied and the purpose for which it will be used, and also
(b) the Researcher must ensure that the information will not be used for any non-research purpose and that the recipient of the information has agreed to conform to the requirements of any relevant Code of Practice.

3 The Researcher must take all reasonable precautions to ensure that Respondents are in no way directly harmed or adversely affected as a result of their participation in a research project.

4 The Researcher must take special care when interviewing children and young people. The Faculty REC will give advice on gaining consent for studies involving children or young people.

5 Respondents must be told (normally at the beginning of the interview) if observation techniques or recording equipment are used, except where these are used in a public place. If a respondent so wishes, the record or relevant section of it must be destroyed or deleted. Respondents' anonymity must not be infringed by the use of such methods.

6 Respondents must be enabled to check without difficulty the identity and bona fides of the Researcher

Appendix XI (b)

Letter of Ethical Approval for this research by Kaduna Ministry of Health, Nigeria.

MINISTRY OF HEALTH, KADUNA STATE

All Communications to be Addressed to:
THE HON. COMMISSIONER
Quoting Reference and Date
Tel: (062) 248084
(062) 248252

Independence Way,
P.M.B. 2014,
Kaduna.
Kaduna State, Nigeria

MOH/ADM/744/VO.I/

27th March, 2012

The Medical Director,

....

....

....

<u>REF: INVESTIGATION INTO FOOTWEAR: CHOICES AND DEMANDS FOR PEOPLE LIVING WITH DIABETIS</u>

I have been directed to convey the Ministry's approval to Irmiya Tagang J of Nigeria Institute of Leather and Science Technology, Zaria to conduct his research on the above topic.

He is requested to submit his findings to the Ministry please.

F. A. Kurah
Secretary, Ethical Committee

Appendix XI (c)

Letter of Ethical Approval for this study by ABUTH Zaria.

Ahmadu Bello University Teaching Hospital

P.M.B. 06, Shika - Zaria, Kaduna State, Nigeria. 069-876305 ·
website: www.abuth.org abuthshika@yahoo.com Abuthshika@gmail.com

Chairman of Board:
Chief Medical Director: DR. LAWAL KHALID, *MBBS, FMCS, FWACS, FRCS(ED) mni*
Chairman, Medical Advisory Committee: DR. ABDULLAHI MOHAMMED, *MBBS, FWACP FICS*
Director of Administration: BARR. ISHAK BELLO, *LL.B, BL, LL.M, PGDM, AHAN, FCAI*

Our Ref:

ABUTH/HREC/TRG/36

27th September, 2012

Mr. Jerry Irmiya Tagang,
De Montfort University
Leicester, U K.

ETHICAL CLEARANCE

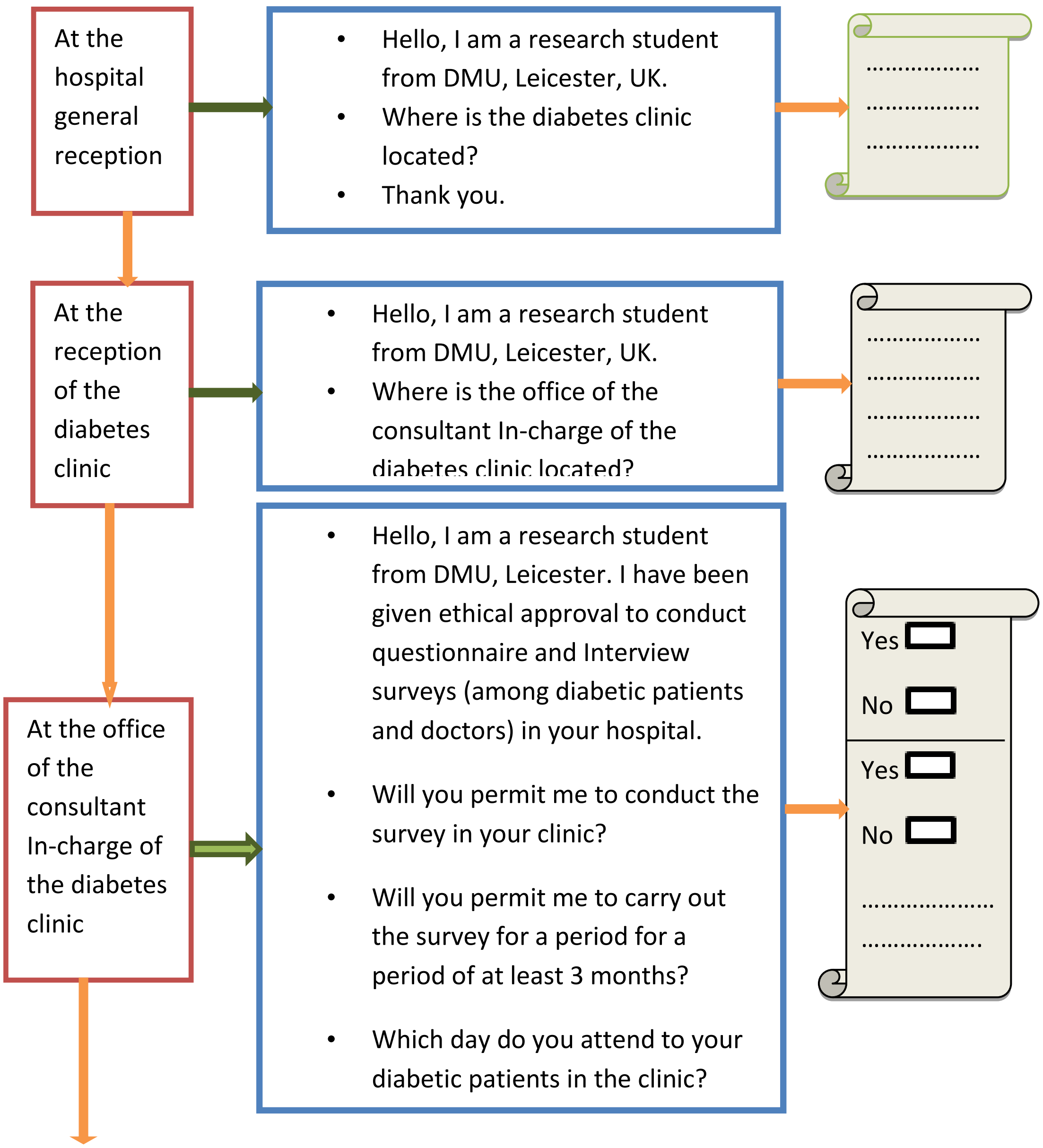
Your application for ethical clearance on the research proposal titled **"An Investigation into Footwear Materials Choices and Design for People suffering with Diabetes"** refers.

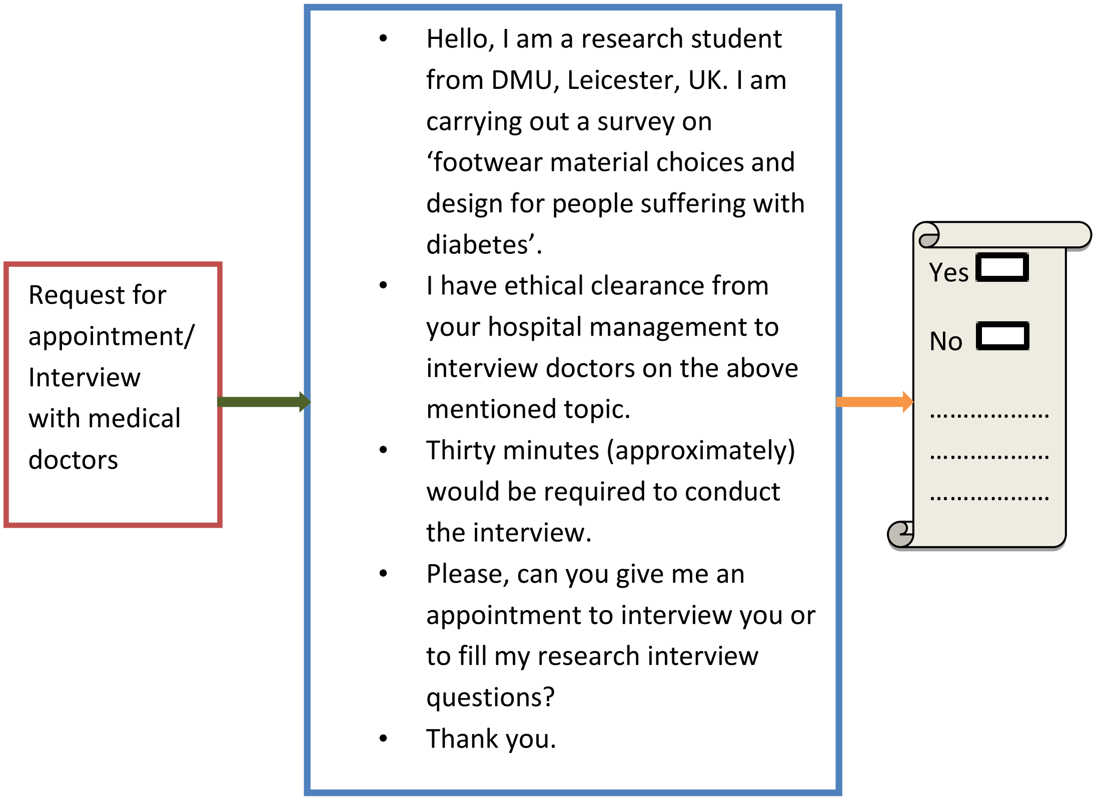
This is to convey ethical approval for you to commence the study. The ABUTH Scientific and Health Research Ethics Committee require an annual update from the Principal investigator.

Prof. Aisha I. Mamman
Asst. Dean PGS
For: Chairman, ABUTH HREC.

Appendix XII
Standard Operating Procedure (SOP) for Interview Survey

Procedure **Enquiry** Response




Request for appointment/ Interview with medical doctors
Hello, I am a research student from DMU, Leicester, UK. I am carrying out a survey on 'footwear material choices and design for people suffering with diabetes'.
I have ethical clearance from your hospital management to interview doctors on the above mentioned topic.
Thirty minutes (approximately) would be required to conduct the interview.
Please, can you give me an appointment to interview you or to fill my research interview questions?
Thank you.
Yes
No
………………
………………
………………

Appendix XIII

Letter of forwarding of results for materials analysis from SON.

STANDARDS ORGANISATION OF NIGERIA

OFFICE OF ZONAL COORDINATOR

Textile/Leather Laboratory,
No 10 Kubau Street,
Kawo New Extension, Kawo,
Kaduna.

Corporate Headquarters:
Plot 1687, Lome Street,
Wuse Zone 7, Abuja
Tel: 09-5239187.
E-mail: info@sononline-ng.org
sonnis_ng@yahoo.com

Operational Headquarters:
Plot 13/14 Northern Business District,
Victoria Arobieke Street,
Lekki Peninsula Scheme 1,
Lekki, Lagos State.
P.M.B. 2102, Yaba.
Tel: 01-2708231-4, 01- 2708230
E-mail: info@sononline-ng.org,
sonnis_ng@yahoo.com
Website: www.sononline-ng.org

Our Ref: SON/KD/LAB/67/VOL/1/83 Your Ref. .... Date: 14th July, 2013.

niya Tagang,
structor,
Nigerian Institute for Leather & Science Research (NILEST),
Zaria- Kaduna State.

FORWARDING OF TEST RESULT

Please find attached test report of samples you sent to us for laboratory analysis through your letter Ref NILEST/PER.339/VOL.II/216 dated 3rd June, 2013.

Kindly acknowledge receipt of this result.

Thank you.

B.D JOSHUA

Head, Textile/Leather Laboratory, Kaduna

For: Director General/Chief Executive (SON)

ALL CORRESPONDENCE TO DIRECTOR - GENERAL

Nigerian Mark of Quality

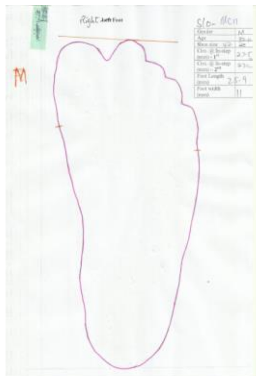
Appendix XIV

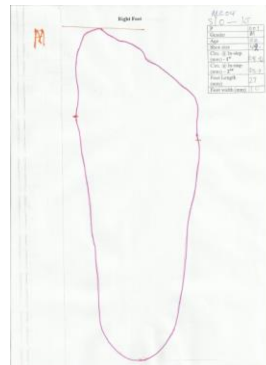
Visited Companies and Organizations

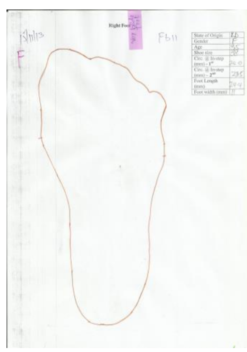
S/No.	Date of visit	Company/ Organization	Contact Persons
1	19-20/10/2011	Naidex South, Excel London, UK	
2	17-19/11/2011	The Design and Technology Association with ICT Show, NEC Birmingham, UK	Andrew Morton (Show Manager)
3	17-18/10/2012	Naidex South, Excel London, UK	Fiona Davies (Event Director)
4	09/11/2012	Foot Care Services, Soletec Systems Limited, 25-27 Park Road, LE11 2ED, Loughborough	Timothy King (Managing Director)
5	14/11/2012	Institute for Creative Leather Technologies, The University of Northampton, Park Campus, Boughton Green Road, Northampton NN2 7AL	Rachel Garwood (Director)
6	15/11/2012	Diabetes Foot Clinic, Royal Infirmary, University Hospitals, Leicester.	Dr. Mary Quinn (Diabetes specialist) Dr. Rajesh Jogia (Podiatrist) Laure Willis (Orthotist)
7	3/12/2012	Bill Bird Shoes Limited, Northwick Business Centre, Gloucestershire, UK.	Bill Bird (Managing Director)
8	02/05/2013	Prosthetics and Orthotics Department, National Orthopaedic Hospital, Kano, Nigeria	Mallam Ja'afaru (Head of Department)
9	16/05/2013	B & B Leather Company, Sharada-Kano, Nigeria	Mallam Bashir (Production Manager)
10	16/05/2013	Unique Leather Finishing Company Ltd, Plot 55/62, Kano, Nigeria.	Stephen Matthew (Head of Department)
11	16/05/2013	FATA Tannery Ltd, Plot 53, Challawa Industrial Estate, Kano, Nigeria	Isuwa Awan (Senior Staff)
12	12/06/2013	Standards Organization of Nigeria, Textile/ Leather Laboratory, Kaduna.	B. D. Joshua (Branch Manager)

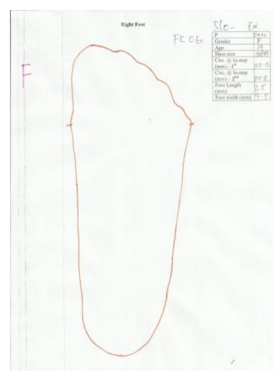
Appendix XV

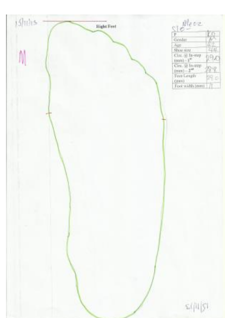
Example of different foot shapes or outlines

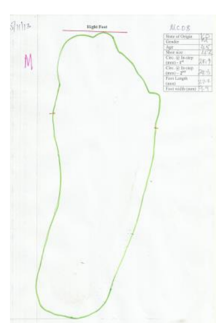












Appendix XVI

Standard Operating Procedure (SOP) for Testing of Trial Prototype

Procedure	Enquiry	Response
At the hospital general reception	Hello, my name is Jerry Tagang. I am a research student from DMU, Leicester, UK. Where is the diabetic clinic located? Thank you	………………… ………………… …………………
At the reception of the diabetes clinic	Hello, my name is Jerry Tagang. I am a research student from DMU, Leicester, UK. Please, where is the office of the consultant In-charge of the diabetes clinic located? Thank you.	…………………… …………………… ……………………
At the office of the consultant In-charge of the diabetes clinic	Hello, my name is Jerry Tagang. I am a research student from DMU, Leicester. I have ethical clearance to conduct my research in your hospital. I have developed a trial prototype of diabetic footwear. Please, will you permit me to sample the opinions of your patients and doctors about the product? Thank you. Thank you.	Yes [ ] No [ ]
With the research participants	Hello, my name is Jerry Tagang. I am a research student from DMU, Leicester, UK. I am carrying out a survey on 'footwear material choices and design for people suffering with diabetes'. I have developed these footwear prototypes based on the outcome of my study. Please, can you spare some few minutes to wear any of this footwear you like most and give me some feedback? Thank you.	Yes [ ] No [ ]

Appendix XVII

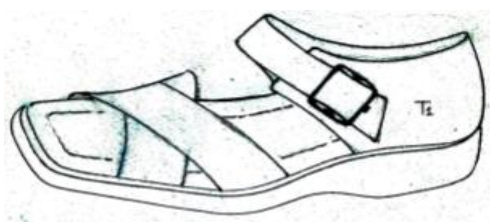
Questionnaire for sampling opinions of diabetic patients on their preferred footwear style.

Project on Diabetic Footwear Design

As part of my PhD studies at De Montfort University, Leicester; I am required to undertake a research study titled: *An Investigation into footwear materials choices and design for people suffering with diabetes.* And at this stage of my study, I am intending to make a trial prototype of diabetic footwear.

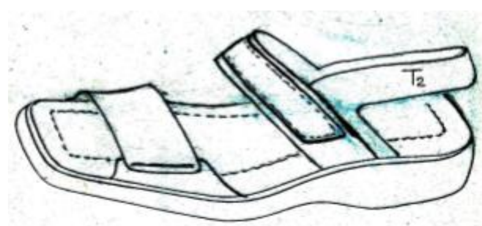
Therefore, you are requested to **Rank** the following footwear styles (with **1** for the most preferred and **12** for the least preferred).

Style 1 [ ]



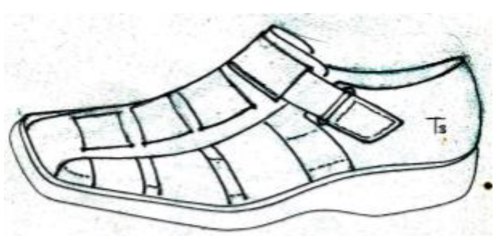
Sole options
* Light weight Microcellular polyurethane (PU), or
*Medium weight microcellular rubber.
Fastener : Buckle
Upper: Full grain side leather.

Style 2 [ ]



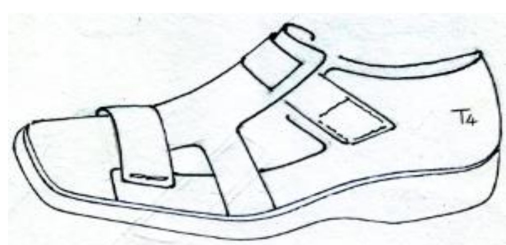
Sole options
*Light weight Microcellular polyurethane (PU), or
*Medium weight microcellular rubber
Fastener:Touch fastener (Velcro)
Upper: Full grain side leather

Style 3 [ ]



Sole options
Dual density PU sole
Or Thermoplastic Rubber (TPR) sole.
Insole: Fixed or Removal Insole.

Style 4 [ ]



Sole options

Dual density PU sole
Or Thermoplastic Rubber (TPR) sole.

Fastener: Buckle or Velcro

Upper: Full grain side leather.

Insole: Fixed or Removal Insole.

Fastener: Buckle or Velcro

Upper: Full grain side leather.

Style 5 [   ]

Sole options: *Dual density PU sole *TPR sole, or *Microcellular EVA sole .

Insole: Fixed or Removal Insole.

Fastener: Elastic strap

Upper: Full grain side leather.

Style 6 [   ]

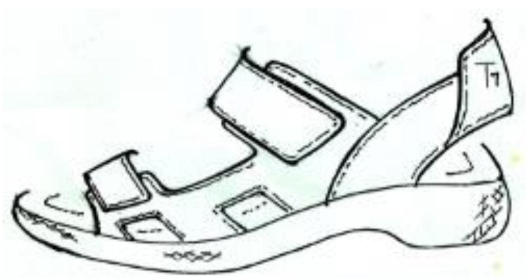
Sole options: Dual density PU sole Or Thermoplastic Rubber (TPR) sole.

Insole: Fixed or Removal Insole.

Fastener: Buckle or Velcro fastener with elastic strap.

Upper: PU coated fabric or Full grain side leather.

Style 7 [   ]

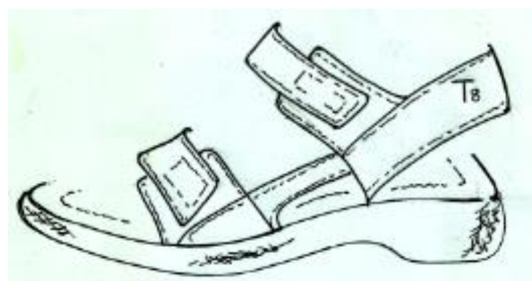


Sole options: *Dual density PU sole*Thermoplastic Rubber (TPR) sole, or*polyvinylchloride (PVC) sole.

Fastener: Velcro fastener

Upper: Full grain side leather.

Style 8 [   ]

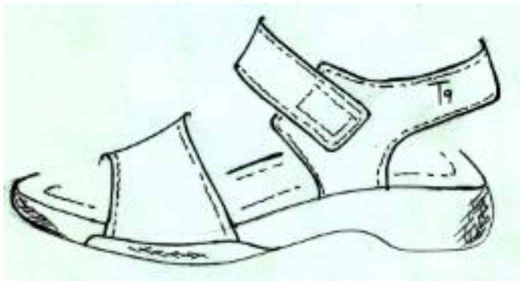


Sole options: *Dual density PU sole**;** *Thermoplastic Rubber (TPR) sole, or; *polyvinylchloride (PVC) sole.

Fastener: Velcro fastener

Upper: Full grain side leather.

Style 9 [ ]

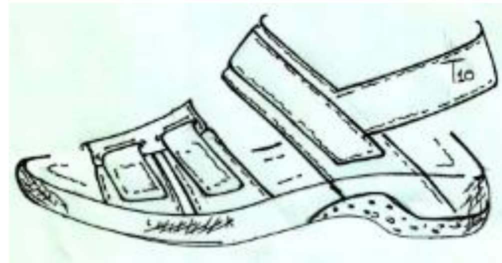


Sole options: *Dual density PU sole; * TPR sole, or *PVC sole.

Fastener: Buckle or Velcro fastener.

Upper: PU coated fabric or Full grain side leather.

Style 10 [ ]

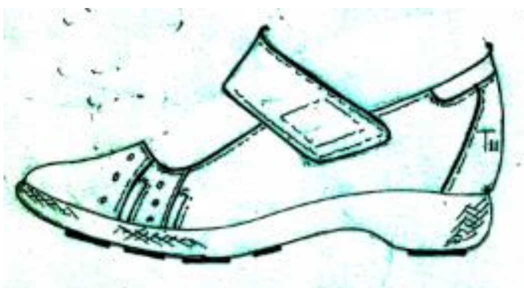


Sole options: *Dual density PU sole**;** *Thermoplastic Rubber (TPR) sole, or *polyvinylchloride (PVC) sole.

Fastener: Velcro fastener

Upper: Full grain side leather, PU coated fabric.

Style 11 [ ]



Sole options: *Dual density PU mid-sole and TPR out-sole**;** *Microcellular EVA mid-sole with TPR out-sole.

Insole: Fixed or removal sole

Fastener: Velcro fastener

Upper: Full grain softee leather or PU coated fabric.

Style 12 [ ]

Sole options: *Dual density PU mid-sole and TPR out-sole**;** *Microcellular EVA mid-sole with TPR out-sole.

Insole: Fixed or removal sole. **Fastener:** Velcro fastener.

Upper: Full grain ‘softee’ leather or PU coated fabric.

Please **tick or mark** [with **X**] the appropriate option.

1. Gender. a. Male [ ] b. Female [ ] c. Do not want to mention [ ]
2. Are you suffering with diabetes? Yes [ ] No [ ]
3. What is your correct shoe size? (please write)………………………………

4. Do you have foot problems that make it difficult for regular shoes to accommodate your feet? Yes [ ] No [ ] **If yes,** please describe (e.g ulcer, gangre, wound, etc)

   ……………………………………………………

5. What type of footwear fastening do you prefer?

   (a) Buckle [ ] (b) Touch fastening (Velcro) [ ] (c) Lace [ ]
   (d) others (please write)……………………………………………………..…

6. When purchasing or selecting footwear, what is your most preferred colour?
   (a) Black [ ] (b) Brown [ ] (c) others (please write)………………..

7. What type of upper materials do you choose for your shoes? You can tick more than one option. a. Leather [ ] b. Synthetic [ ] c. Fabric [ ] d. Others (please write)

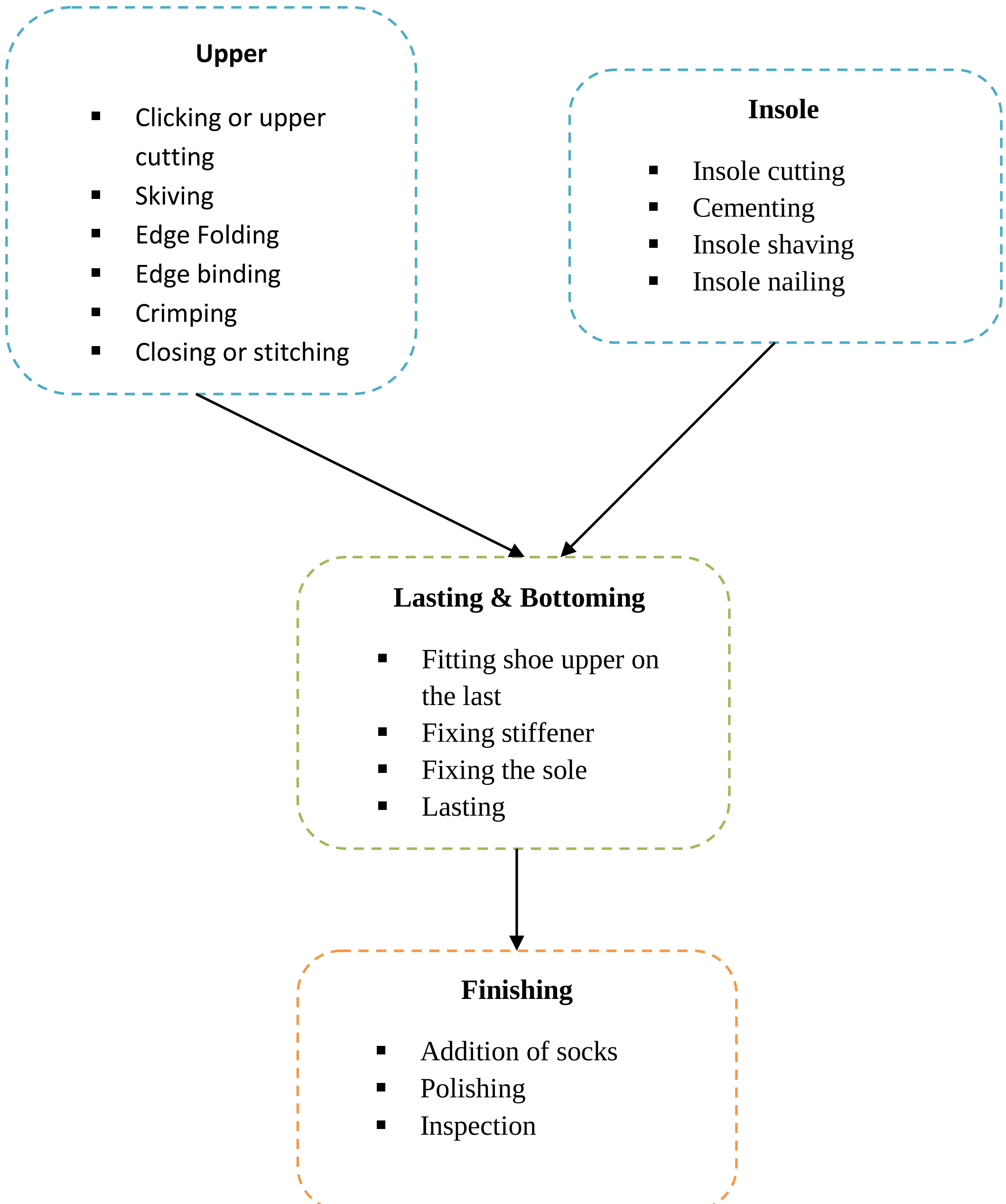
8. Please use the space provided below to describe or sketch your preferred footwear design/ style if you do not like any of the designs presented above.

Thank you.

Jerry Tagang

Appendix XVIII

Major stages/ flow chart of footwear making.



Appendix XIX
Photos of some stages during making of the trial Prototypes



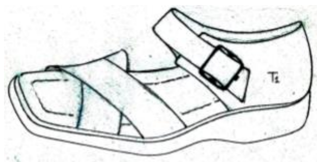




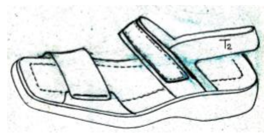



Appendix XX
Questionnaire for testing of trial prototype

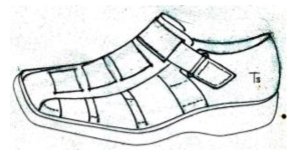
Part I. Visual and cosmetics assessment



Style 1 [ ]



Style 2 [ ]



Style 3 [ ]

1. Do you like the styles of this footwear? Yes [ ] No [ ]
   If no, please write or describe your preferred style……………………………………
2. Which one is your most preferred style? (a) Style I **[**] (b) Style II **[**] (c) Style III **[**]
3. Do you like the color? Yes [ ] No [ ]
   If no, please write your preferred colour……………………………………………..
4. Do you like the materials used for the construction of this footwear? Yes [ ] No [ ]
   If no, what type of materials would you prefer?..
5. By your assessment, is this footwear:
   (a) Very attractive [ ]
   (b) attractive [ ]
   (c) Neutral [ ]
   (d) ugly [ ]
   (e) very ugly [ ]

Part II. Fit and Comfort Assessment

		Yes	**No**
6.	Do the sandals go into your feet easily?	[ ]	[ ]
7.	Is the width of the footwear alright?	[ ]	[ ]
8.	Is the length alright?	[ ]	[ ]
9.	Are you comfortable with the top line?	[ ]	[ ]
10.	Do the fastening aligned properly?	[ ]	[ ]

11. Is the depth of the Instep alright? [ ] [ ]
12. Are you experiencing new pain in any apart of your feet? [ ] [ ]
13. Do you think the footwear is too tight? [ ] [ ]
14. Are you experiencing discomfort in any part of your feet? [ ] [ ]
15. Do you think this footwear should be adjusted in order to accommodate your feet well? [ ] [ ]

Part III. Assessment after footwear is removed from participants' feet.

	Yes	**No**
16. Can you observe any colour change in any part of your feet?	[ ]	[ ]
17. Any swelling in any part of your feet?	[ ]	[ ]
18. Any blisters in any part of your feet?	[ ]	[ ]

19. From your experience, this footwear:
    (a) Will improve walking [ ]
    (b) Is same as own footwear [ ]
    (c) Will not improve walking [ ]

20. This footwear is:
    (a) Very light [ ]
    (b) Light [ ]
    (c) Neutral [ ]
    (d) Heavy [ ]
    (e) Very heavy [ ]

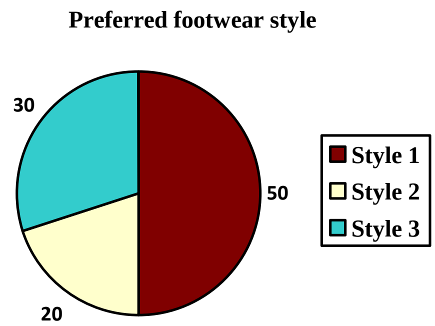
21. How much will you be willing to buy this footwear?
    (a) ₦1000.00 [ ] (d) ₦4000.00 [ ]
    (b) ₦2000.00 [ ] (e) ₦5000.00 [ ]
    (c) ₦3000.00 [ ] (f) ₦5000.00 & above [ ]

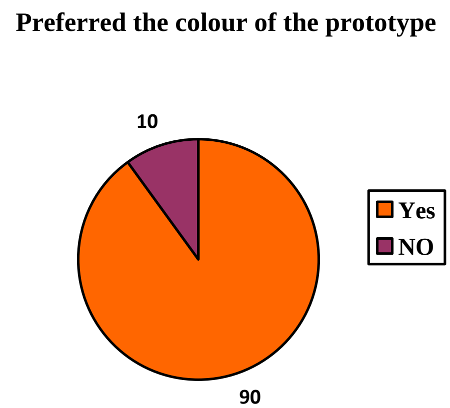
Thank you.

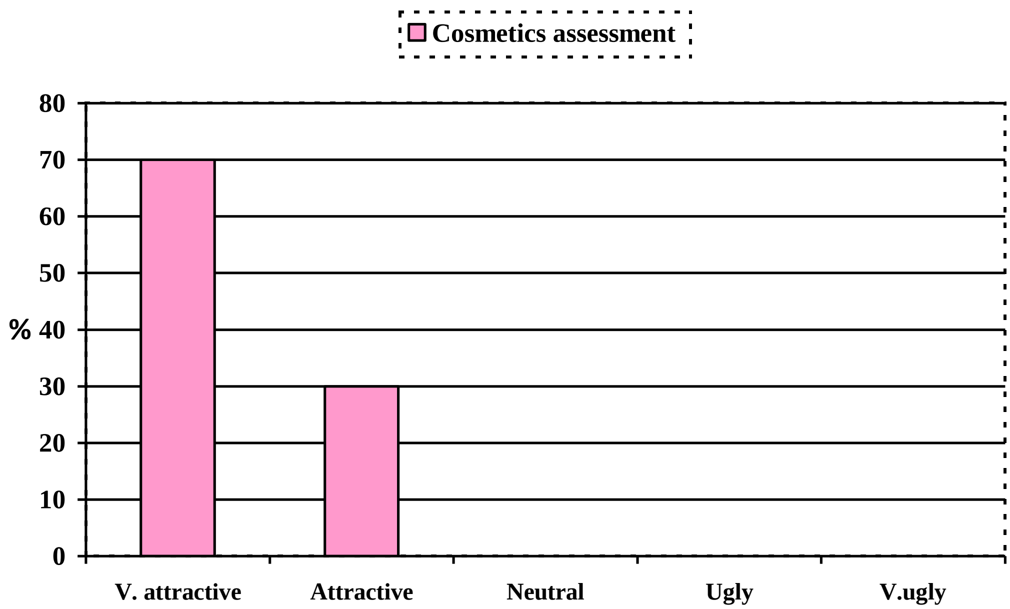
Appendix XXI

Outcome of prototypes pre – assessment

Part I. Visual and cosmetics assessment (n=10)



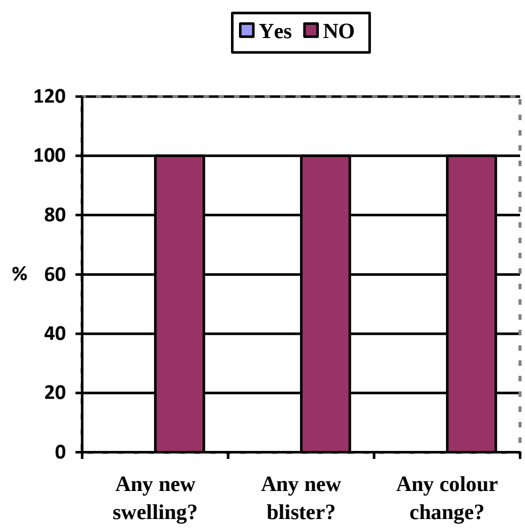


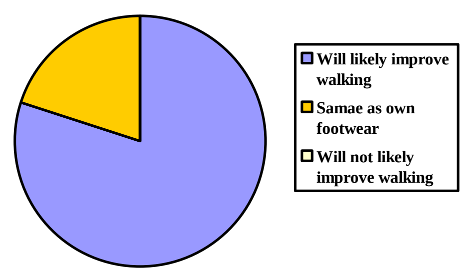


Part II. Fit and Comfort Assessment (n=10)

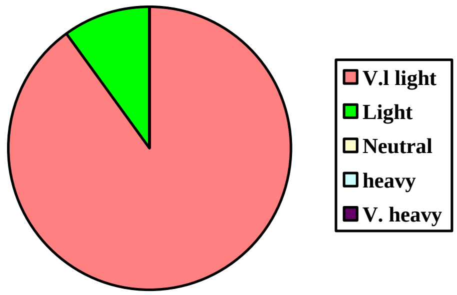
Enquiry		Yes (%)	No (%)
a	Sandals go into the feet easily	90	10
b	Alright with the length of the footwear	90	10
c	Alright with the width of the footwear	90	10
d	Comfortable with the top line	100	0
e	Fastening aligned proprely	90	10
f	Alright with the depth of the Instep	90	10
g	Experience new pains	10	90
h	The footwear is too tight	10	90
i	Experience discomfort	10	90
j	Footwear need to be amended to accommodate feet well	10	90

Part III. Assessment after footwear was removed from the participants' feet. (n=10)

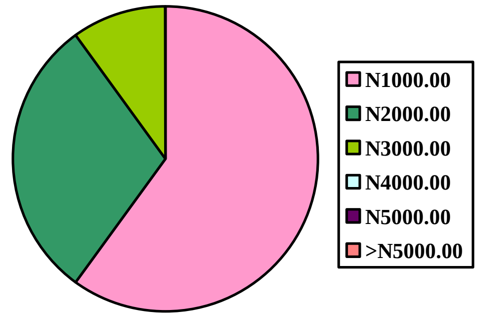




Walking capability



Lightness of the prototypes



Amount willing to purchase the footwear prototype

Note: ₦1:00 is approximately £0.27

Appendix XXII

Contact persons and their addresses for research collaboration between NILEST & ABUTH Zaria, Nigeria.

S/ No.	*Name*	*Institution of Affiliation*	*E-mail address*
1.	Jerry I. Tagang	Nigerian Institute of Leather and Science Technology (NILEST), Zaria.	jerrytagang@yahoo.com
2.	Dr. Isuwa I. Kyari	Nigerian Institute of Leather and Science Technology (NILEST), Zaria.	isuwaadamu@yahoo.com
3.	Dr. Robert Chen	School of Design, De-Montfort University (DMU), Leicester, UK.	rchen1@dmu.ac.uk
4.	Nick Higgett	School of Design, De-Montfort University (DMU), Leicester, UK.	nph@dmu.ac.uk
4.	Dr. Eujin Pei	School of Design, De-Montfort University (DMU), Leicester, UK.	epei@dmu.ac.uk
5.	Dr. Ismail I. Dahiru	Orthopaedic & Trauma Department, Ahmadu Bello University Teaching Hospital, Zaria, Nigeria.	ldismail@yahoo.com

Appendix XXIII

Published Journal Article from this research

Original Article

The role of appropriate footwear in the management of diabetic foot: Perspective of clinicians in a low resource setting

Tagang I. Jerry, Pei Eujin[1], Chen C. Robert[1], Higgett Nick[1], Dahiru L. Ismail[2], Ibrahim Abdulrasheed[3]

Nigerian Institute of Leather and Science Technology, Zaria, Nigeria, [1]School of Design, De Montfort University, Leicester, UK, [2]Departments of Orthopaedic and Trauma, and [3]Surgery, Division of Plastic Surgery, Ahmadu Bello University Teaching Hospital, Zaria, Nigeria

ABSTRACT

Background: The use of appropriate footwear among patients with diabetes mellitus and those with diabetic foot problems has been documented to play a vital role in the prevention and treatment of the established foot disease. However, there is a paucity of literature on the role of clinicians in ensuring appropriate footwear among patients with diabetes mellitus. This paper explores current practice in the use of appropriate footwear in patients with diabetes mellitus among clinicians in Kaduna state, Nigeria.

Materials and Methods: A self-administered structured questionnaire was developed. The questionnaire was divided into two sections: demographic (clinical area of specialization, number of years in practice) and footwear questionnaire. The footwear questionnaire focused on three themes: diabetic foot problems encountered, type of footwear worn, and the role of footwear in the prevention of diabetic foot complications. Data were processed and analyzed using Microsoft Excel 2007.

Results: Almost all the participants, 41 (91%), reported that foot ulcers could be related to inappropriate footwear. Most participants, 37 (82%), reported that ill-fitting footwear could be a major problem that leads to amputation. The shoe type reported to be most frequently worn by men were sandals (35%), slippers (26%), and half shoes (17%). The three commonest shoe types that women were reported to wear were slippers (45%), sandals (24%), and half shoes (18%).

Conclusion: This study shows that the use of appropriate footwear in the prevention of diabetic foot complications is suboptimal. It is important that healthcare professionals support and stimulate research in establishing a diabetic footwear program.

Key words: Clinicians, diabetes, foot complications, footwear

Introduction

Lower limb complications in diabetes mellitus are a frequent and seriously disabling condition.[1,2] Diabetic foot syndrome is one of the most devastating complication affecting both the quality of life and health care utilization.[3-5] It is the leading cause of lower limb amputation, generally preceded by foot ulcers and gangrene. Foot ulceration may occur in up to 15% of diabetic patients during their lifetime and about 15-25% of people with a foot ulcer will require an amputation.[6-8] In addition to the morbidity, diabetic foot complications are associated with high mortality; 50% will die within 5 years of an initial major amputation.[4,8,9]

Address for Correspondence: Dr. Abdulrasheed Ibrahim, Department of Surgery, Division of Plastic Surgery, Ahmadu Bello University Teaching Hospital, Zaria, Nigeria. E-mail: shidoibrahim@yahoo.com

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The major risk factors for diabetic foot complications are peripheral neuropathy, peripheral vascular disease, and foot deformity. However, inadequate or inappropriate footwear is also thought to be an important contributor to these complications.[10,11] Ill-fitting footwear is a common trigger for foot ulceration, as it exposes the patient to the direct effects of friction and/or irritation as well as indirect damage because of inappropriate foot protection. Inappropriate footwear causing increased mechanical stress at the plantar and dorsal surfaces of the foot has been reported as the most common cause of foot ulceration in patients with diabetes.[12,13] Footwear should be designed to relieve pressure areas, reduce shock, and shear forces and be able to accommodate deformities by supporting and stabilizing them. It is necessary that shoes fit for both size and shape.[6,14] When footwear is fitted properly, it can reduce high pressure areas and hence reduce callus formation and the threat of ulcer formation. It will also fulfill its function as a barrier to the environment.[6]

Diabetic foot complications and amputations persist despite the availability of preventive interventions.[8] The International Working Group on the Diabetic Foot has published recommendation for appropriate choice of footwear that may reduce the risk of foot ulceration and amputations. These guidelines emphasize that appropriate footwear is an important cornerstone in the care of patients with diabetes mellitus.[11] There is a paucity of literature on the role of clinicians in ensuring appropriate footwear among diabetics in Nigeria and indeed sub-Saharan Africa. Given the need for a common outcome in health care delivery globally, this article explores current practice in the use of appropriate therapeutic footwear in patients with diabetes mellitus among clinicians.

Materials and Methods

A cross-sectional descriptive study was conducted in Kaduna, (the capital of Kaduna state, north central Nigeria) during the period January through March 2013. All clinicians involved in the management of the diabetic foot and its complications were invited to participate in the study. The study was approved by the research ethics committee at the Ministry of Health, Kaduna State and at Ahmadu Bello University Teaching Hospital, Zaria, Nigeria. Participants at the beginning of the study were given information on the nature of the survey, the participants' right to withdraw from the study at any time, and confidentiality of personal data. In order to maintain confidentiality, questionnaires were made anonymous.

A self-administered structured questionnaire was developed. The questionnaire was divided into two sections: Demographic (clinical area of specialization, number of years in practice) and footwear questionnaire. The footwear questionnaire focused on three themes: Diabetic foot problems encountered, type of footwear worn, and the role of footwear in the prevention of diabetic foot complications. The questionnaire included a range of open-ended questions as well as closed questions with the answer options as true or false. Data were processed and analyzed using Microsoft Excel 2007. Simple descriptive statistics were used (frequency with percentage distribution for categorized variables).

Results

Out of the 60 clinicians surveyed, 45 returned the questionnaire, giving a response rate of 75%. A total of 30 (67%) had been practicing for 6-20 years. In all, 20 (45%) were orthopedic surgeons, whereas 15 (33%) were endocrinologists [Table 1].

The frequency of diabetic foot problems encountered is shown in Table 2. Almost all the participants, 41 (91%) reported that foot ulcers could be related to inappropriate footwear. Most participants, 37 (82%) reported that ill-fitting footwear could be a major problem that leads to amputation. More than 50% of the participants had encountered patients that reported bad footwear experience.

The distribution of the commonest footwear worn by gender is shown in Figure 1. The reported shoe types most frequently worn by men were sandals (35%), slippers (26%), and half shoes (17%). The three commonest shoe types that women were reported to wear were slippers (45%), sandals (24%), and half shoes (18%). Slippers were owned by (71%) of men and women, whereas only 1% of

Table 1: Demographic profile of participants

Variable	Number	%
Number of years in practice		
<5	9	20
6-20	30	67
>21	6	13
Area of specialization		
General practice	10	22
Orthopedic surgery	20	45
Endocrinology	15	33

Table 2: Participant's response to diabetic foot problems encountered and the role of footwear

Diabetic foot problems	Yes number (%)	No number (%)
Have encountered patients that reported bad footwear experience (e.g. blisters, ulcers, etc)	27 (60)	18 (40)
Foot ulcers could be related to inappropriate footwear	41 (91)	4 (9)
Ill-fitting footwear could be a major problem that leads to foot amputation	37 (82)	8 (18)
Regular shoes are unable to accommodate the foot of many diabetes patients	31 (68)	14 (32)

men and women were reported to wear custom-made or therapeutic footwear.

A total of 81% of participants reported that their diabetic patients will be happy to use orthopedic/therapeutic footwear [Table 3]. More than 90% of the participants were of the opinion that there was no foot care or footwear program for patients with diabetes in their practice. All the participants agreed that medical specialists will benefit from education on prescription of therapeutic footwear.

Discussion

Our study highlights the need for the use of appropriate footwear to prevent diabetic foot complications in this part of the world. Majority of the patients are reported to have foot problems and these are related to the wearing of ill-fitting or inappropriate footwear. This contributes significantly to the susceptibility of the diabetic foot to injury and ulceration. This scenario is not different from what has been previously reported.[5,15] Foot complications from inappropriate footwear continue to exact a very high cost on society as a result of the associated disability, morbidity, and mortality.[11] Jannink and his colleagues advocate the regular use of proven therapeutic interventions (footwear) in the prevention of diabetic foot complications.[16] This should be sought and promoted because of the potential cost effectiveness and improved outcome for the patient. It has been shown that it is possible to reduce amputation rates by between 49 and 85% through a foot care strategy that combines the following: prevention, a multidisciplinary approach in the use of appropriate footwear, close monitoring, and the education of people with diabetes and healthcare professionals.[17] However, in most countries, foot care is not yet at the level of funding, organization, and professionalism that would facilitate the ready attainment of these objectives. These goals are feasible and affordable in many contexts, and it is possible to learn from settings where standards are being set.[17]

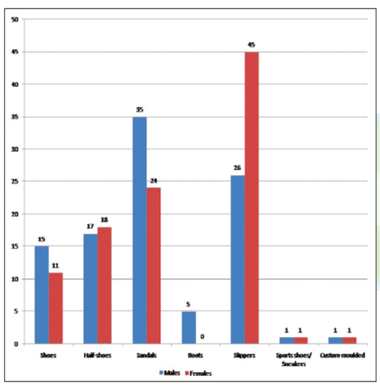

Figure 1: The distribution of footwear worn by gender

Table 3: Participants response to the role of appropriate footwear in the prevention of diabetic foot

Footwear and prevention of diabetic foot	Yes number (%)	No number (%)
Diabetic patients would be happy to use orthopedic footwear	36 (81)	9 (19)
Footwear should be regarded as an important consideration in the clinical management of foot problems	44 (97)	1 (3)
Foot care program for diabetic patients are not available in Nigeria	41 (91)	4 (9)
Footwear program for diabetic patients are not available in Nigeria	43 (95)	2 (5)
Provision of professional foot care (podiatric services) is not common in Nigeria	39 (87)	6 (13)
The risk of foot amputation may double for diabetic patients who do not obtain prescribed footwear	41 (91)	4 (9)
Doctors are unaware of orthopedic footwear makers in Nigeria	(71)	(29)
Clinicians need further education about prescription of orthopedic footwear	45 (100)	0 (0)

In this study, patterns of footwear were generally similar for both men and women except for the more frequent use of open toe footwear (slippers) by women. Furthermore, it was also observed that the type of footwear considered most appropriate for patients with diabetes mellitus to use (custom-molded shoes) were the least frequently worn. This finding is similar to an earlier study that revealed that provision of professional diabetic foot care services and the use of protective diabetic footwear were suboptimal in both developing and developed countries.[8] Rubbing from footwear was identified as the definite cause of 35% of foot ulcers reviewed as part of a prospective study conducted in the United Kingdom. Similarly, the follow-up of 472 patients at the Royal Prince Alfred Hospital Diabetes Centre (NSW, Australia) identified that 54% of all foot ulcers that developed in this group could be directly attributed to trauma from footwear.[7] The consistent use of appropriate footwear is important in all diabetic patients, especially those who demonstrate loss of protective sensation from peripheral neuropathy. These patients are unable to feel pressure or pains caused by inappropriate or ill-fitting shoes and are more likely to develop blisters, callus, and corns. These early complications require prompt intervention if ulceration and potential amputation are to be avoided. The simple measure of wearing appropriately fitted or prescribed footwear has been shown to significantly reduce plantar foot pressures, therefore decreasing the likelihood of developing callus and ultimately ulceration.[7]

This study has some limitations. Participants were selected based on their willingness to participate in the study. They could thus represent clinicians who were actively involved in the care of patients with diabetes mellitus and diabetic foot complications and therefore may not reflect the spectrum of footwear practices delivered by clinicians in Kaduna state. A second weakness is the nature of the subject population — clinicians. There is a lack of perspective of the patients. For a complete view of the role of diabetic footwear in the prevention of diabetic foot complications, their opinion should be included. Future research is thus required to compare the perceptions of clinicians and patients. Additionally, prospective studies that evaluate the impact of footwear practices on outcomes such as neuropathy, foot ulcers, and amputations would further help to determine the potential for interventions to improve practice and reduce complications.[8] To further obtain valid data on the role of appropriate footwear in patients with diabetes mellitus, a comparative study of the type of footwear in patients that have had surgeries and patients that have not had surgical intervention will be important. We also believe that publication of these findings will serve as a catalyst for further studies in the subject area, where clinicians and researchers can evaluate the extent to which appropriate practices are being followed in their setting.

Conclusion

This study demonstrates that the use of appropriate footwear in the prevention of diabetic foot complications is suboptimal. It is important that healthcare professionals support and stimulate research in establishing a diabetic footwear program in Kaduna state. Accurate data collection from multicenter studies will assist health policy decision makers to allocate resources efficiently to a state footwear program. This will lead to improved outcomes for patients at risk of diabetic foot complications.

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Glossary of Some Terms

Amputation: Removal of part or all of a body part enclosed by kin. For example, removal of part of a toe or an entire toe would be termed an amputation. Removal of an appendix, on the other hand, would not be termed amputation. A person who has undergone an amputation is called an amputee.

Blister: A collection of fluid underneath the top layer of skin (epidermis). One that is more than 5mm in diameter with thin walls and is full of watering fluid is called a bulla or a bled.

Breathability: This is technically known as water vapour permeability; the ability of a material to absorb and transmit moisture.

Diabetes: Is a condition where the amount of glucose in your blood is too high because the body cannot use it properly. This is because your pancreas does not produce any insulin, or not enough, to help glucose enter your body's cells- or the insulin that is produced does not work properly (known as insulin resistance).

Diabetic neuropathy: A family of nerve disorders caused by diabetes. Diabetic neuropathies cause numbness and sometimes pain and weakness in the hands, arms, feet, and legs. People with diabetes can develop nerve problems at any time, but the longer a person has diabetes, the greater is the risk.

Disease: Illness or sickness often characterized by a typical patient problems (symptoms) and physical findings (signs).

Dorsum: The top surface of the foot.

Family: 1. A group of individuals related by blood or marriage or by a feeling of closeness. 2. A biological classification of related plants or animals that is a division below the order and above the genus. 3. A group of genes related in structure and in function that descended from an ancestral gene. 4. Parents and children. The most fundamental social group in human.

Foot: The end of the leg on which a person normally stands and walks. The foot is an extremely complex anatomic structure made up of 26 bones and 33 joints that must work together with 19 muscles and ligaments to execute highly precise movements. At the same time, the foot must be strong to support more than 100,000 pounds of pressure for every mile walked. Even small changes in the foot can unexpectedly undermine its structural integrity and cause pain with every step.

Footwear: Is outer coverings for the feet, such as shoes, boots, sandals, etc.

Gait: The way of walking.

Health: A state of complete physical, mental, and social well-being, not merely the absence of disease or infirmity.

Instep: The surface of the foot which is on top and in front of the ankle.

Insulin: Is a hormone produced by the pancreas that allows glucose to enter the body's cells, where it is used as fuel for energy so we can work, play and generally live our lives. It is vital for life.

Nerves: A bundle of fibers that uses chemical and electrical signals to transmit sensory and motor information from one body part to another.

Neuropathy: Any and all disease or malfunction of the nerves.

Off-the-shelf footwear: Shoes available from normal shoe outlets.

Pain: An unpleasant sensation that can range from mild, localized discomfort to agony. Pain has both physical and emotional components. The physical part of pain results from nerve stimulation. Pain may be contained to a discrete area, an injury, or it can be more diffuse, as in disorders like fibromyalgia. Pain is mediated by specific nerve fibers that carry the pain impulses to the brain where their conscious appreciation may be modified by many factors.

Peripheral vascular disease: A disease of blood vessels outside the heart. Peripheral vascular disease (PVD) affects the peripheral circulation, as opposed to the cardiac circulation. PVD comprises of both peripheral arteries and peripheral veins. PVD is sometimes incorrectly used as a synonym for peripheral artery disease (PAD). Intermitted claudication due to inadequate blood flow to the leg is an example of peripheral vein disease.

Product Design Specification (PDS): Is a listing of key parameters, specifications and requirements (e.g materials: light weight) prepared at the outset of any design activity. It is intended to show what a designer is trying to achieve, not what he will end up with.

Skin: The skin is the body's outer covering. It protects against heat and light, injury, and infections. It regulates body temperature and stores water, fat, and vitamin D. Weighing about 6 pounds, the skin is the body's largest organ. It is made up of two main layers; the outer epidermis and the inner dermis.

Trauma: Any injury, whether physical or emotionally inflicted. "Trauma" has both a medical and a psychiatric definition. Medically, trauma refers to a serious or critical bodily injury, wound, or shock. The definition is often associated with trauma medicine practiced in emergency rooms and represents a popular view of the term. In psychiatry, "trauma" has assumed a different meaning and refers to an experience that is emotionally painful, distressful, or shocking, which often results in lasting mental and physical effects.

Ulcer: An area of tissue erosion, for example, of the skin or lining of the gastrointerstinal (GI) track. Due to the erosion, an ulcer is concave. It is always depressed below the level oof the surrounding tissue.

Sources for glossary of terms

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